

An Exploration into the Efficacy of Home-Based Interpretive Bias Modification Programmes
on Emotional Pathology

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Abstract

This research portfolio sought to examine and extend current evidence around the potential for home-based Cognitive Bias Modification (CBM) training to retrain interpretive biases and improve emotional pathology. To this aim, 12 published studies exploring this potential in depression and anxiety were systematically reviewed. Overall, evidence for clearer training effects appeared to follow studies for which CBM targeted depressive interpretive biases, which typically adopted a different delivery modality for the training. Studies exploring CBM utility in anxiety-based presentations were less homogenous in their clinical focus. A common confound in this research appeared to be lack of between-group differences due to unanticipated improvements in control groups. An empirical study is then presented, which explored the efficacy of a home-based CBM package targeting worry in an older adult sample reporting generalised anxiety symptomology. Six individuals participated in this non-concurrent multiple baseline study involving a seven-day CBM training phase and follow-up. The study identified a moderate response to CBM, in which half the sample showed evidence of training improvements in daily well-being measures. Overall changes in diagnostic scores of generalised anxiety symptomology indicated statistically reliable but not clinically meaningful progress. Performance data provided key insight into potential moderating factors affecting CBM efficacy, such as anxiety-related interference of engagement with the training. Despite the study's originality in terms of both the sample's age cohort and clinical presentation, the results largely coincide with the 12 reviewed studies. The portfolio concludes with recommendations for future research, with advice to extend the age range of study samples to include appropriate lifespan representation.

List of Contents

Acknowledgements	iv
Thesis Portfolio Introduction.....	5
Chapter 1. Systematic Review	6
Abstract	8
1.1. Introduction	9
1.2. Method	12
1.3. Results	14
1.4. Discussion	31
1.5. Conclusions	37
References	39
Chapter 2. Bridging Section.....	47
Chapter 3. Quantitative Research Paper.....	49
Abstract	51
3.1. Introduction	52
3.2. Method	55
3.3. Results	63
3.4. Discussion	70
3.5. Conclusions	74
References	76
Chapter 4. Extended Methodology.....	85
Chapter 5. Extended Analysis.....	88
Chapter 6. Overall Discussion and Critical Appraisal.....	95
References.....	110
Appendices.....	119

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Thesis Portfolio Introduction

Cognitive bias modification (CBM) is an experimental paradigm designed to retrain individuals' proclivity to interpret ambiguity in a threatening manner. Since the techniques inception, nearly twenty years ago, research has sought to explore the potential for CBM to be clinically applied. A recent focus in this development has involved investigations over the extent to which training effects transfer from the laboratory into more naturalistic settings. With current hopes that CBM might offer an easily resourced clinical aid to supporting individuals with emotional pathology, establishing successful generalisation across these settings is key to the success of the field.

This thesis portfolio explores the current stage of progress towards developing a clinical CBM package through its focus on research investigating home-based CBM training efficacy. The opening two chapters of this portfolio are presented in the format of self-contained scientific papers: a systematic review of current evidence, followed by the reporting of a quantitative study that was conducted to extend current knowledge. Subsequent chapters are dedicated to the description of additional material and more extensive statistical analysis of the empirical data, and to integrating the findings in a final discussion and critical appraisal.

**Chapter 1. Systematic review prepared for submission to the Journal of Anxiety
Disorders**

**A systematic review of home-based interpretive cognitive bias modification (CBM)
training**

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Abstract

This review aims to summarise and evaluate the findings from 12 published studies that explored the efficacy of home-based multi-session interpretive cognitive bias modification (CBM) programmes. Evidence supporting clear superiority of CBM compared to control training paradigms is inconsistent, and often only shown through additional hypothesis-driven analyses. These patterns are argued to potentially reflect a poor choice of comparison group owing to the common unanticipated finding of improvements in ‘control’ groups. Such a methodological limitation is widespread to many included studies, and creates challenges in firmly asserting a conclusion regarding training efficacy. Generally, findings indicate a moderate potential for CBM to effect positive changes in depressive and anxious symptomology. Improvements were more consistently identified in literature directed towards depression, which is likely due to the more homogenous nature of such sample groups compared to the more expansive range of disorders that fall under ‘anxiety disorder’ classifications. Further research is required to determine a clearer understanding relating to the clinical applicability of CBM procedures. Suggestions for specific areas of focus or quality improvements in research design are discussed.

Keywords: interpretive bias, cognitive bias modification, depression, anxiety, clinical, home-based

1.1. Introduction

The identification of a link between the prevalence and maintenance of psychopathology and biases in an individual's information processing styles (e.g. Eysenck, Mogg, May, Richards, & Mathews, 1991) has understandably prompted considerable interest in the hope of furthering our knowledge of how to effectively alleviate associated distress. While these views have long formed the central tenets of cognitive models of anxiety and depression (e.g. Beck, 1987; Beck & Clark, 1997), the emergence of research aimed at directly measuring and modifying cognitive biases in information processing has offered a more tangible medium to explore these links.

This scientific investigation of identified cognitive biases has primarily focused on two areas: how individuals typically attend to (attentional bias) or interpret (interpretive bias) threat-based information when presented with ambiguity. With regards to interpretive biases, which forms the focus of this review, efforts to experimentally 'train' a more positive style of processing information typically involves the repeated practice of resolving ambiguity in a non-threatening manner (Mathews & Mackintosh, 2000). Individuals are required to take an active role in this exercise, to facilitate the reinforcement process. The most commonly used interpretive CBM paradigm involves scenarios-based training (Mathews & Mackintosh, 2000). For this, individuals are required to read and imagine themselves in a series of scenarios that are presented sequentially on a computer screen, one line at a time. Each scenario remains ambiguous until the final word, which is presented as a word fragment for individuals to solve. Successful resolution elucidates the meaning of the entire situation in a threat-focused or benign manner. A simple comprehension question follows, to highlight the underlying meaning. A typical example might include a description of giving an invited speech at a friend's wedding during which you become distracted by people laughing. The

benign interpretation would involve the guests appreciating the humour of the speech, while the threatening explanation would allude to mocking laughter.

Training effectiveness can be determined through the identification of changes in interpretive bias, measured pre- and post- training, that correspond to training valence. The most common method of assessing bias involves the use of the Ambiguous Scenarios Test (AST; Mathews & Mackintosh, 2000), where individuals are presented with a series of scenarios to read through that remain ambiguous in nature. Following this, individuals are presented with four statements for each scenario; describing a relevant (target) positive and negative interpretation, and a general (foil) positive and negative interpretation. Individuals are required to give a resemblance rating for each sentence according to their recollection of the original scenario. These ratings reflect individuals' recalled interpretations of the ambiguous content, thus providing a measure of biased information processing. The addition of foil as well as target interpretations affords a level of control against generalised response biases.

More recently, an alternative measure used to assess interpretive bias that has proved popular is the scrambled sentences test (SST; Wenzlaff, 1993). For this, individuals reorganise strings of words to form legible sentences. The SST is far quicker to administer, although incorporates no control for generalised bias in the way the AST manages to. Efforts to increase the validity of this test include the feature of an added cognitive load (Bowler et al., 2012), such as having the process timed or adding an additional memory task to the assessment. This load is designed to overwhelm an individual's capacity to consciously respond, which aims to protect against effortful processing of sentences and foster an accurate measure of natural threat propensity.

Early investigations of CBM training have heralded the paradigms success in managing to train a more positive or negative interpretive bias, according to the consistency with which these situations resolve in a neutral or threat-focused manner (Mathews & Mackintosh, 2000; Wilson, MacLeod, Mathews, & Rutherford, 2006). CBM training has been argued to produce robust changes in interpretive biases that are independent of changes in mood (Salemink & van den Hout, 2010), survive across changes in assessment context (Mackintosh, Mathews, Yiend, Ridgeway, & Cook, 2006), and sustainable across time (Yiend, Mackintosh, & Mathews, 2005). Following this establishment, focus has turned to exploring the clinical utility of interpretive CBM through investigating whether the training successfully altered interpretive biases in specific clinical populations, and whether doing so effected change in associated symptom prevalence or severity. The format of CBM training means that the content can be tailored to match theoretically-assumed underlying principles of targeted presentations. Individual studies investigating both the impact of a single training session (e.g. Amir, Bomyea, & Beard, 2010; Hayes, Hirsch, Krebs, & Mathews, 2010; Mathews, Ridgeway, Cook, & Yiend, 2007; Murphy, Hirsch, Mathews, Smith, & Clark, 2007) or multi-session training packages (e.g. Beard & Amir, 2008) have reported promising indications for the clinical potential of CBM. However, following recent reviews that caution a more tentative opinion (e.g. Hallion & Ruscio, 2011; Mobini, Reynolds, & Mackintosh, 2013) and criticise poor study quality (e.g. Cristea, Kok, & Cuijpers, 2015), consensus remains unsettled.

One of the principal claimed benefits that hypothetical clinical CBM paradigms might hold over current intervention techniques, whether as their replacement or in some adjunct form, lies in the reduced resource demand required for delivery. The technique has no need for protected physical clinic space, and the independent administration of the training means it can be immediately accessed without the need for expensive service provision. Further, in

an era of economic austerity, the current rate of missed outpatient appointments represents a massive financial burden for health services, estimated at £225 million between 2012 and 2013 (National Audit Office, 2014). In addition, missed appointment rates generate extended waiting lists that can unnecessarily obstruct access to care (Murray, 2000). Alternatively, inconsistent engagement with CBM training would carry minimal financial implications and consequences to care provision. This is contingent on the method being ultimately developed as a package that can be accessed in the community. Accordingly, more studies are being published that address the efficacy of independently managed (i.e. home-based) multi-session computerised CBM packages. Although some such studies have been included in the aforementioned reviews, the relatively recent surge of studies targeting this means that the area has not been appropriately represented previously. The aim of this review, therefore, is to identify whether the published literature to date provides collective evidence to support the potential for multi-session interpretive CBM programmes that operate away from the laboratory to improve interpretive biases and targeted emotional pathology. Owing to the current unresolved opinion around the efficacy of CBM, this area seems justified in specific exploration both to identify current trends and to inform future research and programme development.

1.2. Method

This review was conducted according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA; Moher, Liberati, Tetzlaff, & Altman, 2009). To identify suitable articles for review, searches were conducted across six online databases (MEDLINE, PubMed, PsychINFO, Science Direct, Web of Science, and EMBASE) on 23rd December 2016. Each search adopted the same strategy: three separate searches were performed utilising Boolean search terms to combine commonly referenced terminology. These searches related to the three distinct focal points of this review: (1) cognitive bias

modification [cognitive bias modification OR cbm OR bias training OR bias modification]; (2) specific to interpretive bias [interpret OR interpretation OR interpretive OR interpretative NOT (attention OR attentional)]; and (3) mode of training [home OR internet OR online]. These separate searches were then combined into a single search to identify articles that specifically fulfilled all three criteria. To provide comprehensive cover, reference lists of included articles were also manually scanned, as were specific clinical trial websites (www.clinicaltrials.gov and www.who.int/trialsearch), and author searches were conducted for key individuals.

Specific pre-determined inclusion criteria mandated that papers reported a self-contained study (1) that adhered to the above search strategy; (2) for which data collection had been completed; (3) that contained more than one training session (no upper limit set); and (5) that used a version of training that was similar in format to Mathews and Mackintosh's (2000) original ambiguous scenarios training. A pre-defined exclusion criterion was set for CBM interventions that were intended as vicarious training tools, in which targeted outcomes were measured in individuals who did not necessarily complete CBM training (e.g. as parenting tools). Information was exclusively collected from articles published in English, available through online peer-reviewed journals.

Given the review question, no inclusion criteria were set relating to study design, participant population, or clinical presentation. For this reason, methodological quality and risk of bias was more broadly considered through reference to the distinct quality categories described in Higgins and Green (2011). This flexible approach was considered to permit comment on the comparative methodological quality across the studies, rather than provide robust evaluations of individual study quality.

1.3. Results

A total of 15,345 studies were initially identified through the search strategy described above, which was condensed to 745 studies specifically focusing on interpretive CBM training, and further to 55 studies when controlling for the training environment. Of those, 12 studies satisfied all additional inclusion criteria (see Figure 1.1). Key characteristics of the included studies are provided in Table 1.1.

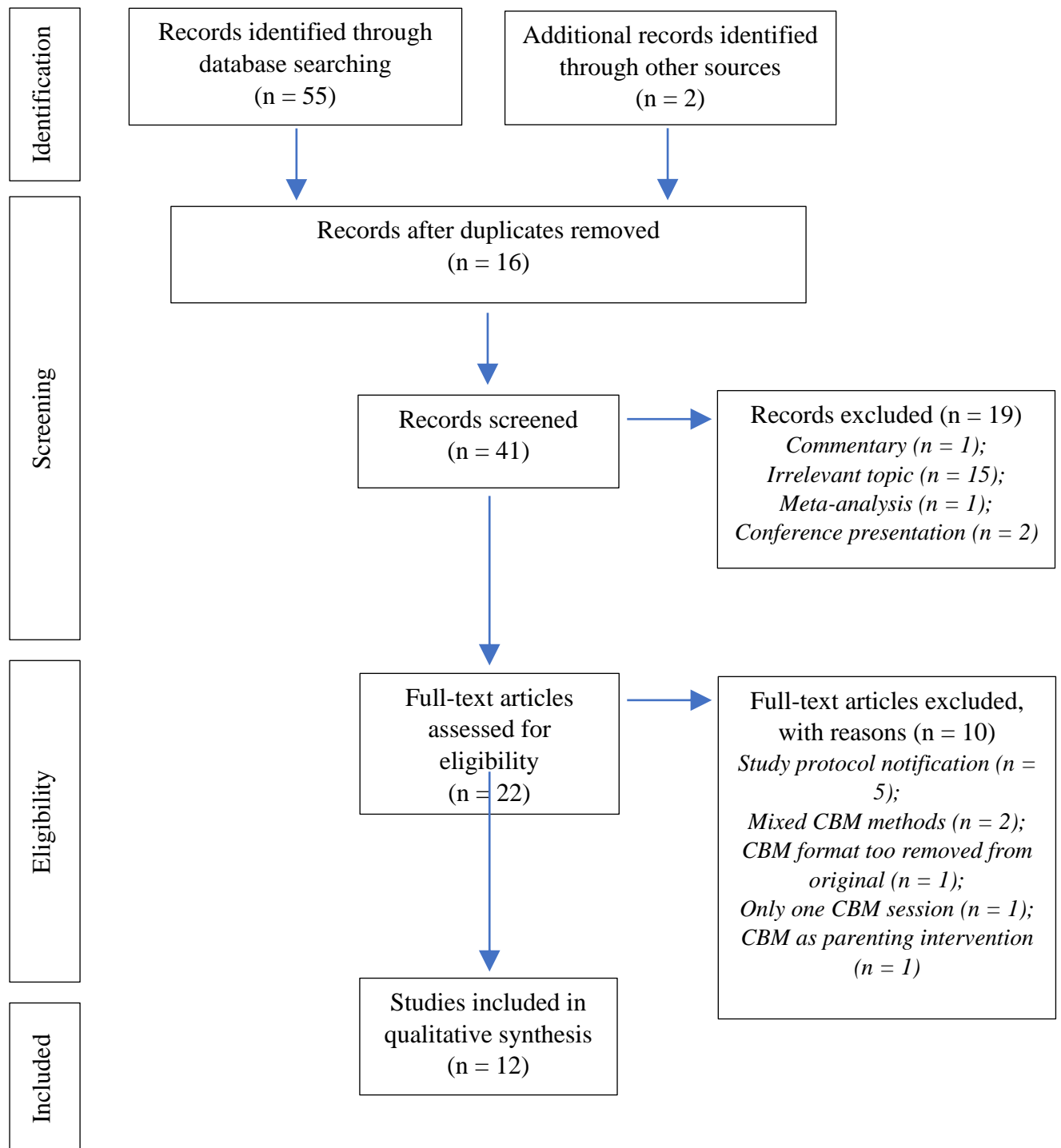


Figure 1.1. PRISMA flow diagram for study selection

Table 1.1

Key Study Characteristics and Findings

Author; publication year	Study design; Country	Focus; Sample	Screening	Female split; Mean age (SD)	Bias Measurement		Key outcome measures	No of CBM sessions and mode of delivery	Group	N	Main findings	
					Task	Measured					On bias	On OMs
Blackwell et al. (2015)	RCT; UK	Depression; Clinical	BDI-II >13;	59.5%	SST	Baseline	BDI-II;	6x Aud 6xpic:word	CBM	76	Reduction in negativity scores for both groups	<ul style="list-style-type: none"> Both groups: improved BDI-II scores CBM group showed greater improvement in anhedonia, and more pronounced improvement in BDI score in participants with <5 episodes of depression
			SCID-I MDD module	35.5 (13.9)		Post- intervention			CBMc	74		
Blackwell and Holmes (2010)	A-B single case series; UK	Depression; Clinical	BDI-II >14; SCID-I MDD module	71% 37.7 (15.2)	SST	Baseline Post- intervention	BDI-II; SCL-90-R; VAS	7x Aud	CBM	7	Trend decrease in negativity scores	<ul style="list-style-type: none"> 4/7 participants were identified as 'responders', showing improvements in mood due to training Improvements maintained after 2 weeks 3/7 identified as 'non-responders'

Butler et al. (2015)	Intervention study; Australia	Social anxiety; Analogue	SPIN >18	70% 24.1 (6.9)	AST	Baseline Post-intervention 2 week follow up	SPIN; CDS; WSAS	3x Read (3xcCBT)	cCBT+ CBM cCBT+ CBMn	20 20	<ul style="list-style-type: none"> Improved for both groups CBM group showed significantly higher improvements for target items on top of that, which were maintained at 2w FU 	<ul style="list-style-type: none"> Improved scores for OMs, but no significant interaction by group Larger effect sizes were evident for cCBT +CBM group
Hoppitt et al. (2014)	Intervention study; UK	Anxiety; Analogue	n/a	80% All aged between 18-35 (further details not reported)	AST	Baseline Post-intervention	FNE; STAI; PANAS	5x Read	CBM BT	35 34	<ul style="list-style-type: none"> Both groups showed improved general biases (i.e. not exclusive to target items) Stronger improvements evident in CBM group 	<ul style="list-style-type: none"> Reduction in social anxiety following CBM only No change in state/trait anxiety or PANAS
Lang, Blackwell, Harmer, Davison, and Holmes (2012)	Intervention study; UK	Depression; Clinical	SCID-I MDD module	77.5% 28.5 (8.9)	SST	Baseline Post-intervention	BDI-II; HRSD; STAI-t; IES	3x Aud 2xpic:word 1x appraisals 1x mixed	CBM CBMc	13 13	<ul style="list-style-type: none"> Improved bias in CBM group only 	<ul style="list-style-type: none"> CBM group showed significant improvements in depressive symptoms (BDI-II and HRSD)

Pictet, Jermann, and Ceschi (2016)	Intervention study; France	Depression; Analogue	BDI-II >13	79% 26.7 (9.1)	AST-D	Baseline Post-intervention 2 week follow up	BDI-II; STAI-t; SHAPS; TEPS	4x Aud	CBM CBMc WLC	34 34 33	<ul style="list-style-type: none"> • Improved bias in CBM group only 	<ul style="list-style-type: none"> • BDI-II: Improved for CBM and CBMc groups, but more pronounced following CBM • Improvements maintained after 2 weeks • SHAPS: Improved anhedonia for CBM and CBMc groups • Improvements maintained after 2 weeks
Salemink, Kindt, Rienties, and van den Hout (2014)	RCT; The Netherlands	Mixed anxiety; Clinical	SCID-I anxiety disorder modules	67% 38 (9.9)	AST Superseded training items	Post-intervention	STAI; BDI; SCL-90; PANAS	8x Read	CBM CBMc CBMn	18 18 19	<ul style="list-style-type: none"> • AST: CBM group showed more positive bias than control group, but not specific to target items • Training items: CBM group showed preference for positive items over negative items, and slower response time for negative items compared to control groups 	<ul style="list-style-type: none"> • All groups showed improvements in trait anxiety (STAI), depressive symptomology (BDI), and psychiatric distress (SCL-90) • All maintained after 3 months • No change in PANAS or STAI-s

Salemink, van den Hout, and Kindt (2009)	Intervention study; The Netherlands	Anxiety; Analogue	STAI-T >44; Negative bias based on group mean	83% 21.3 (2.1)	AST Superseded training items ASSIQ	Post-intervention (Pre + post intervention)	STAI; FNE; SCL-90; VAS	8x Read	CBM CBMc	17 17	<ul style="list-style-type: none"> • Training items: CBM group showed training effect to training items but not to new items; no change for CBMc group • AST: Training effect evident but only when measured immediately (<24hrs) in same context • No change in ASSIQ 	<ul style="list-style-type: none"> • CBMc group showed increases in state anxiety that were not evident in CBM group • Trait anxiety (STAI-t) and psychiatric distress (SCL-90) reduced in CBM but not CBMc group • No training effects on reported distress to stress test
Salemink, Wolters, and de Haan (2015)	Intervention study; The Netherlands	OCD; Clinical	CY-BOCS >7	63% 15.4 (2.2)	ASToc Superseded training items	Baseline Post-intervention	OBQ-CV; CY-BOCS; RCADS; CDI	8x Read	TAU (CBT) +CBM TAU (CBT) +CBMn	9 7	<ul style="list-style-type: none"> • ASToc: Equal improvements across groups • Training items: Reduced response speed to OC probes in all groups 	<ul style="list-style-type: none"> • Fewer OC symptomology (CY-BOCS obs) and improved anxiety (RCADS) in CBM group only • No change at all for depression (RCADS) • Improved reported obsessive beliefs (OBQ-CV) and compulsive behaviours (CY-BOCS comp) for all

Torkan et al. (2014)	Intervention study; Iran	Depression; Clinical	SCID-I	64% 27.6 (2.1)	SST	Baseline Post-intervention 2 week follow up	BDI-II; STAI-t	7x Aud	CBM CBMni WLC		• Significant decrease in negativity score in CBM group only	• Improvement in BDI-II in CBM and CBMni group only; significantly greater for CBM group • Reduced trait anxiety across all groups
Williams, Blackwell, Mackenzie, Holmes, and Andrews (2013)	RCT; Australia	Depression; Clinical	MINI	76% 44.8 (12.1)	AST-D SST	Baseline Post-intervention	BDI-II; PHQ-9; K-10	7x Aud	CBM then cCBT WLC then cCBT	38 31	• SST: No change in either group • AST-D: No sig diff between group means, but significant improvement in bias in CBM group that not evident in WLC group	• Significant improvement in BDI-II, PHQ-9, and K-10 scores for both groups, but significant more for CBM group • Change found to be mediated by trained bias changes (AST-D)
Williams et al. (2015)	RCT; Australia	Depression; Clinical	MINI	73% 41.9 (11.4)	AST-D	Baseline Post-intervention	PHQ-9; BDI-II; K-10	7x Aud	CBM then cCBT CBMc then cCBT	36 39	• Improved across both groups significantly	• Significant improvements in all measures in both groups that were maintained after 3 months

Note. For *Screening*: BDI-II = Beck Depression Inventory; SCID-I = Structured Clinical Interview for the DSM-IV; SPIN = Social Phobia Inventory; STAI = Spielberger State-Trait Anxiety Inventory; CY-BOCS = Children's Yale-Brown Obsessive Compulsive Scale; MINI = Mini International Neuropsychiatric Interview. For *Bias Task*: SST = Scrambled Sentences Test; AST = Ambiguous Scenarios Test; AST-D = depression-specific AST; ASSIQ = Ambiguous Social Scenarios Interpretation Questionnaire; ASToc = obsessive-compulsive-specific AST. For *Outcome Measures*: SCL-90 = Symptom Checklist-90; PANAS = Positive and Negative Affect Schedule; VAS = Visual Analogue Scale; CDS = Cognitive Distortions Scale; WSAS = Work and Social Adjustment Scale; FNE = Fear of Negative Evaluation Scale; HRSD = Hamilton Rating Scale for Depression; IES = Impact of Events Scale; SHAPS = Snaith-Hamilton Pleasure Scale; TEPS = Temporal Experience of Pleasure Scale; OBQ-CV = Obsessional Beliefs Questionnaires - Child Version; RCADS = Revised Children's Anxiety and Depression Scale; CDI = Children's Depression Inventory; PHQ-9 = Patient Health Questionnaire-9; K-10 = Kessler-10 Psychological Distress Scale. For *Group*: CBM = Interpretive Cognitive Bias Modification; CBMc = CBM control group (training

content included an even balance of positive/negative resolutions); cCBT = computerised cognitive behaviour therapy; BT = brain training task; WLC = waitlist control; CBMn = CBM without emotional content (neutral); TAU = treatment as usual; CBMni = CBM with no imagery content.

1.3.1 Efficacy of Home-Based CBM Interventions

1.3.1.1 Interpretive biases. Eleven studies measured interpretive biases both prior to and following the CBM phase, thus improving the accuracy with which it is possible to attribute training-induced changes. Of these, only three studies identified clear training effects in which biases improved in groups that received CBM only (Lang et al., 2012; Pictet et al., 2016; Torkan et al., 2014). All three of these studies targeted depressive presentations, but measured interpretive biases using a mixture of tools. Three further studies revealed findings that suggest some level of between-group differences indicative of some (weak) level of training-specific change (Butler et al., 2015; Hoppitt et al., 2014; Williams et al., 2013). Blackwell and Holmes' (2010) single case series similarly suggested some evidence of training-induced improvements in interpretive bias. The remaining four studies (Blackwell et al., 2015; Salemink et al., 2009; Salemink et al., 2015; Williams et al., 2015) revealed no between-group differences. Using the more typically employed Ambiguous Scenarios Test, which participants completed at the post-intervention stage only, Salemink et al. (2009) did identify training-associated changes in interpretive bias. However, these patterns were limited to participants who had completed this measure immediately following the final training session within the same context. When analyses included data from an additional 20% of participants who experienced unexpected technical difficulties and so completed the same measure 24 hours later at a research facility, this training effect was no longer significant ($F = 1.44$). The more recent included study conducted by this research team (Salemink et al., 2014) suggests similar potential but weak training effects; participants in the CBM group showed a more positive bias compared to participants in CBMc or CBMn groups². As these

² CBMc = control training with equally balanced positive/negative resolutions of scenario; CBMn = emotionally neutral training content; see Table 1.1 notes for further detail.

patterns were revealed both for target and foil items, however, they are more likely to reflect a more generalised positive response bias.

1.3.1.2 Targeted difficulty. 1.3.1.2.1 Depression. With one exception (Williams et al., 2015), all studies that investigated the impact of home-based CBM interventions on depressive symptomology show at least some evidence of training effects. The clarity of these effects, however, varied significantly. With the most convincing evidence, Lang et al. (2012) and Torkan et al. (2014) produce results to suggest clear improvements in clinical measures of depressive symptoms in clinical samples who receive CBM with an imagery component; patterns that are not evident in matched samples who receive a control version of the training or wait-list controls. Next, in their single case series, Blackwell and Holmes (2010) argue that the evidence that 57% of their clinical sample showed a positive response to CBM training is on par with expected response rates to current psychological or pharmacological treatments for depression. Blackwell et al. (2015) and Pictet et al. (2016) demonstrate that CBM might directly target specific facets of depression, with their evidence of greater improvements in anhedonia measures. The former study additionally provides evidence that recurrence of depression might be a key component to its successful application, as between-group differences emerged in overall depressive symptom improvement when the number of episodes of depression was accounted for.

1.3.1.2.2 Anxiety. Most studies exploring the efficacy of home-based CBM programs on anxiety presentations used an analogue sample of University students. These studies provide some evidence for hypothesised training effects, but not in a consistent manner. For example, Salemink et al. (2009) observed increases in anxiety symptoms in participants that received an active control training that were not evident in CBM groups, who instead show reductions in trait anxiety and psychiatric distress. However, these changes do not augment reactions to a subsequent laboratory stress test, with no between-group differences in distress.

Similarly, Hoppitt et al.'s (2014) findings demonstrate a reduction in social anxiety prior to starting a university degree in participants who receive CBM training that is not evident in participants who complete a control brain training task. Yet measures of state or trait anxiety, along with positive and negative affect, remain unchanged in both groups. Two studies, one with an analogue (Butler et al., 2015) and one a clinical (Salemink et al., 2015) sample, show results indicating a generally improved presentation across groups with CBM leading to a slightly superior position. Whereas Salemink et al. (2014), who adopt a sample of participants with mixed clinical anxiety disorders, find no evidence of CBM-specific improvements.

1.3.3 Importance of CBM Training Characteristics

1.3.3.1 Delivery of training. The majority of included studies opted for a single mode of training delivery, either favouring having participants read through the scenarios from a computer screen or listen to them being read aloud through headphones. Two studies (Blackwell et al., 2015; Lang et al., 2012) used a mixed presentation method; combining auditory presented scenarios training with a non-scenarios-based interpretive bias training. Preference for each method appears to follow the explored presentation, with auditory delivery styles being used in studies on depression, while studies exploring anxiety adopt the original form of having participants read through the scenarios. Interestingly, all tests of bias require participants to read through materials to activate interpretive threat biases.

1.3.3.2 Number of training sessions. Studies varied according to the number of CBM sessions that participants were required to complete during the intervention stage, ranging from three to eight sessions ($mean = 6.08$, $SD = 1.80$). Seven of the 12 studies adopted a daily training regime, with three studies allowing a few additional days for flexibility. Two studies utilised a less intensive training schedule: Blackwell et al. (2015) staggered training requiring participants to adhere to a daily schedule for the first week,

followed by a less intensive schedule for the following three weeks. Alternatively, participants in Hoppitt et al.'s (2014) study were afforded a time schedule that required training to be completed less regularly than alternate days. An average of 33.21 minutes ($SD = 14.77$) was calculated using data from the seven studies that reported time taken to complete training. Training schedules did not appear to be linked to the variable efficacy of CBM training.

1.3.4 Methodological Quality

1.3.4.1 Study design. 1.3.4.1.1 Measurement of bias. As already mentioned, 92% of studies included in this review measured interpretive bias prior to and following the CBM training. Studies additionally varied in their preferred tool used to measure this. While all five studies exploring the links between CBM home-based training programs and anxiety used the traditional Ambiguous Scenarios Test, the majority of studies focusing on depression opted to measure interpretive bias using the Scrambled Sentences Test. The three studies focusing on depression that did employ the Ambiguous Scenarios Test used a variant that had been developed to specifically explore depressive interpretive biases (Berna, Lang, Goodwin, & Holmes, 2011). For the anxiety-focused studies, all but one study used the original variation of the task (Mathews & Mackintosh, 2000), which includes scenarios based around general and social anxiety. Salemink et al. (2015), who explored obsessive compulsive presentations, utilised a variant that featured specific symptom-relevant scenarios for that population (Salemink & van den Hout, 2010).

1.3.4.1.2 Use of control group. The use of a 'control' group to compare group differences was varied. Five studies included a control version of the CBM training where scenarios remained the same but the contingency between a positive or negative resolution was balanced (rather than being fixed in a positive manner). In an effort to provide further

control, Saleminck et al. (2014) additionally included a training group in which the scenarios included non-emotional content. Despite their efforts, the resulting symptom-related changes reflected those in the CBMc and CBM groups. Hoppitt et al. (2014) used an alternative active control group where participants completed 'brain training' consisting on non-emotive content, reasoning that the task trained visuospatial ability. Interestingly, the identification of possible training effects on depressive symptomology by Williams et al. (2013), who compared CBM to a wait-list control group, led to the research group repeating the study using an active CBMc comparison group (Williams et al., 2015). This study, as previously mentioned, failed to identify clear between-group differences. As an exception, Torkan et al. (2014) included an active control group in which participants also completed positive CBM (delivered through headphones) with the difference that this version of training omitted the instruction and guidance encouraging the use of imagery. Participants in this group (CBMni) showed training effects on depressive symptomology, but to a comparatively subsidiary extent to individuals who completed positive CBM with an imagery focus. Torkan et al. (2014) and Pictet et al. (2016) were the only studies to include both a time-controlled wait-list group and an active intervention group.

1.3.4.1.3 Mixed intervention. Four studies feature a mixed intervention, combining CBM training with Cognitive Behaviour Therapy (CBT). Williams et al. (2013; 2015) separated out the two aspects, providing participants with a week of CBM training followed by 10 weeks of computerised CBT. Saleminck et al. (2015) included a study sample who were receiving manualised CBT to explore the potential additive effects of CBM, while Butler et al. (2015) devised a training strategy in which participants alternated daily between cCBT and positive or neutral CBM training.

1.3.4.2 Study conduct. In addition to study characteristics identified in Table 1.1, Table 1.2 lists details specifically pertaining to methodological quality across the studies included in this review.

1.3.4.2.1 Demographic. Every study included in this review contained a female-dominant sample, with the lowest, most-balanced sample containing a 59.5% representation of females, and the highest featuring an 83% dominant sample. Across the studies, females accounted for a mean of 71.92% ($SD = 7.14$) of the overall population. The included studies also seemed to favour a young-middle aged adult cohort, with a mean cross-study age of 31.05 years old ($SD = 8.76$). Removal of age data from Salemink et al.'s (2015) study, which specifically targeted an adolescent sample, only raised this average marginally ($mean = 32.61$ years, $SD = 7.59$).

1.3.4.2.2 Randomisation and blinding. All studies reported that participant allocation occurred according to a randomised process (where study design made this appropriate), with six studies describing having used some method of electronically generating a randomisation sequence, and the remaining five simply listing the process as “random”. Only one study (Blackwell et al., 2015) provided detailed information relating to demographic and symptom-based group stratification. By contrast, only three studies (Blackwell et al., 2015; Salemink et al., 2014; Williams et al., 2015) incorporated double-blinding procedures for group allocation. Although, Lang et al. (2012) did include some level of control for researcher bias through the use of blind independent raters for a sub-selection of outcome measures. All other studies gave no mention of blinding procedures, which was conservatively interpreted as none being employed.

1.3.4.2.3 Adherence. Seven studies provided information relating to participant compliance to the training, with reported levels showing a good level of adherence. Exactly half of the studies provided details about how adherence was monitored.

1.3.4.2.4 Participant feedback. Participant views on completing CBM training were collected in only half of the included studies, with four of those six limiting feedback to quantitative ratings on Likert scales. In their single case series study, Blackwell and Holmes (2010) collected more extensive feedback from participants that was applied to the study procedure to enhance subsequent participation experience. Further qualitative information was collected in this and Torkan et al.'s (2014) study around individuals' approaches to processing training content to explore whether this adopted a more verbal or imagery style.

Table 1.2

Key Study Methodological Quality Criteria

Author; publication year	Power calculation	Randomisation process	Blinding		Informed purpose of CBM	Baseline between- group comparisons	Treatment of missing data	ITT	Adherence to training	Method of monitoring adherence	Overall attrition (N)	CBM feedback
			P	R								
Blackwell et al. (2015)	Yes	Electronic randomisation system	Yes	Yes	NR	Completed; no mention of how differences accounted for	No action	Yes	88% completed >50% of sessions in CBM group; 69% in control group (no statistical difference)	Reminders sent; monitored online; missed sessions prompted contact	2	Quantitative feedback collected
Blackwell and Holmes (2010)	NR	n/a	n/a	n/a	Initially none, then informed like “mental keep-fit” following feedback	n/a	NR	n/a	3 sessions missed by 2 participants; 1 participant completed majority at research facility	NR	0	Procedural feedback refined protocol; qualitative data on processing collected
Butler et al. (2015)	NR	Electronic randomisation system	NR	NR	NR	Completed for demographic details only	NR	NR	NR	NR	NR	Quantitative feedback collected
Hoppitt et al. (2014)	NR	“Random” with the restriction that N kept approximately equal across groups	NR	NR	Informed that ability to imagine self in various situations may reduce anxiety	Completed; no further action required	NR	NR	All completed >80% training sessions, other than 1 participant who was removed	NR	5	NR
Lang, Blackwell, Harmer, Davison, and Holmes (2012)	NR	Electronic randomisation system	NR	No, but sub- selection of interviews independently blindly rated	NR	Completed; differences accounted for in analysis appropriately ³	NR	NR	All completed >85% training sessions	NR	2	NR

³ Term used when statistical analyses are conducted to identify/control for between-group differences (e.g. covariate analyses).

Pictet, Jermann, and Ceschi (2016)	Yes	“Random”	<i>NR</i>	<i>NR</i>	<i>NR</i>	Included in efficacy analyses	No action	Yes	All completed >94% training sessions	Monitored online; reminders sent	0	<i>NR</i>
Salemink, Kindt, Rienties, and van den Hout (2014)	Refers to one but no further details	Electronic randomisation system	Yes	Yes	Investigation of computer training for anxiety	Completed; differences accounted for in analysis appropriately	No action	Yes	<i>NR</i>	Monitored online daily	10	<i>NR</i>
Salemink, van den Hout, and Kindt (2009)	<i>NR</i>	“Random”	<i>NR</i>	<i>NR</i>	Not introduced as treatment, no mention of any beneficial effects	Completed; differences accounted for in analysis appropriately	<i>NR</i>	<i>NR</i>	<i>NR</i>	Monitored online daily	<i>NR</i>	<i>NR</i>
Salemink, Wolters, and de Haan (2015)	<i>NR</i>	“Random”, stratified on gender, age, and school level	<i>NR</i>	No	Testing a potentially new type of treatment	Completed; no further action required	No action	<i>NR</i>	<i>NR</i>	<i>NR</i>	0	<i>NR</i>
Torkan et al. (2014)	Yes	“Random”	<i>NR</i>	<i>NR</i>	<i>NR</i>	Completed; no further action required	No action	<i>NR</i>	All completed >85% training sessions	No monitoring, but retrospectively verified adherence	0	Quantitative feedback collected; qualitative data on processing collected
Williams, Blackwell, Mackenzie, Holmes, and Andrews (2013)	Yes	Electronic randomisation system	<i>NR</i>	<i>NR</i>	<i>NR</i>	Completed; no further action required	Intent-to-treat marginal models using restricted maximum likelihood estimation	Yes	<i>NR</i>	<i>NR</i>	CBM=7; cCBT=6	Quantitative feedback collected
Williams et al. (2015)	Yes	Electronic randomisation system	Yes	Yes	<i>NR</i>	Completed; no further action required		Yes	61% for CBM; 68% for cCBT	Through computer; reminder sent daily	CBM=7; cCBT=0	Quantitative feedback collected

Note. *NR* = Not reported; Blinding *P* = Participant blinding procedures; Blinding *R* = Researcher blinding procedures; CBM = Interpretive cognitive bias modification; cCBT = computerised cognitive behaviour therapy.

1.4. Discussion

This review aimed to synthesise and evaluate the current evidence for home-based cognitive bias modification for interpretive biases that feature a scenarios-based training paradigm to improve interpretive bias and associated emotional pathology. The findings from the 12 included studies produce a consistently inconclusive sense of potential with regards to this question. Frequently, individual studies have alluded to the clinical capacity of CBM training, but often only following a hypothesis-driven more extensive and conditional exploration of the data. The degree of this further investigation varies across studies, however the prevalence seems common to all bar three studies. One study (Blackwell & Holmes, 2010) adopted a single case series design, where individual participants act as their own control thus removing the option for between-subject analyses (Kazdin, 2011). Alternatively, Lang et al. (2012) and Torkan et al. (2014) identified hypothesis-consistent findings demonstrating a clear positive response to the intervention CBM training that was not evident in control comparison groups.

The included studies share several key design characteristics, whose homogeneity might have inadvertently concealed the probability of identifying clear between-group differences. Most noticeable of these is the choice of comparison interventions that are employed. Seven studies used a version of training for this purpose that remained identical to CBM training with the exception that the ambiguous nature of the scenarios resolved equally in a positive/benign and threatening manner. This design relies on the assumption that it is the consistency with which scenarios are positively resolved that provides the therapeutic capacity of CBM. Holmes, Mathews, Dalgleish, and Mackintosh (2006) argue the importance of including explicit instruction and potentially specific training to encourage and support engagement with the training using a visual rather than verbal processing style to enhance CBM potential. It is possible, therefore, that the mere design of the ‘control’ training

repeatedly used in the current studies encouraged an individual awareness of habitual responses to ambiguity, which led to a more concerted effort by the participant to remedy this. The lack of collection of qualitative information removes the possibility of testing this idea retrospectively, and emphasises the importance of enriching quantitative data with qualitative feedback to obtain a holistic sense of participants' experiences. However, such a proposal might reasonably account for the common findings of improved symptomology or changes in interpretive bias in the comparison groups of five of these seven studies.

An alternative reasoning for the lack of unity in findings across studies might be a result of the varying methodological designs used. This review included four randomised controlled trials (RCTs), one single case series, and seven experimental designs that were not identified as RCTs. A full account of the advantages and disadvantages to each design is beyond the scope of this review, however there are several specific restrictions to each that should be noted due to their relevance to the observed findings discussed here. The use of a single case series design nullifies the need for a control comparison group, as each individual acts as their own independent control (Kazdin, 2011). The utility of this is in the reduced requirement for large participant samples, making it a useful design for feasibility research prior to the investment of funding into larger-scale projects (see J. Smith, 2012 for a review). Further, a recent review discussing the progress of CBM research has identified the need for more such design to balance out the field (Fox, Mackintosh, & Holmes, 2014). The absence of a matched control group, however, removes the possibility of providing comment on the exclusive potential of interventions. In this review, for example, it is possible to interpret Blackwell and Holmes' (2010) findings of a 57% response rate to CBM as encouraging but inclusion of these findings in commentary around the comparative potential of control versus CBM training is not permissible. The comparison of the two types of between-groups intervention studies (RCT and non-RCT) is more feasible providing the process is completed

with appropriate caution. Owing to the stringent criteria relating to study design and reporting, RCTs clearly afford a greater control over factors that commonly contribute to research biases. For example, blinding procedures safeguard against researcher influence or participant response biases, while statistical power calculations merit the validity of findings (Clark & Mulligan, 2011). Where non-RCT intervention studies included in this review have not referred to such procedures, it has been conservatively assumed that they have not been implemented. This point is particularly pertinent here given the high potential risk of bias that might explain changes that the clinical potential of the training is otherwise founded on. This opinion has been previously presented by Cristea, Kok and Cuijpers (2015) in their pejorative meta-analysis, which concluded that the literature around CBM was fraught with low quality studies.

A second quality conduct and reporting criteria that warrants mention here relates to how information around adherence to study protocol was promoted and captured. An obvious benefit to home-based CBM interventions lies with its reduced resource demand. This advantage is negated, therefore, if adherence is dependent on frequent supervision. For the seven studies that reported data on training compliance, fidelity seemed high. However, the three studies that additionally provided information relating to in-vivo monitoring procedures described rigorous schedules that involved daily reminders and individual pursuit following missed sessions. More specific to the exploration of efficacy, compliance data might reveal useful explanations for differences in findings. For example, while initial findings indicated significant improvements across groups for outcome measures in Williams et al.'s (2015) study, a 'per-protocol' analysis that controlled for training compliance (held at 100%) revealed a significant group interaction. Participants in the CBM group showed significant decreases in BDI-II scores following training, and in BDI-II and K-10 scores following the additional cCBT phase that were not evident in the control training group. No changes were

found to impact on interpretive bias, however, with improvements evident across both groups.

Relatively few studies collected feedback from participants around their experiences of completing CBM training. This is surprising given the known subjective complaint that CBM training can feel repetitive (Beard, 2011; Chan, Lau, & Reynolds, 2015). Interestingly, quantitative data from Butler et al. (2015) did reveal higher reported dissatisfaction in response to completing training, which did not entirely correspond to outcome. This suggests that perceived acceptability might not detrimentally impact training potential as might be assumed. Nevertheless, this undoubtedly remains an area that requires further attention prior to clinical application as the success of any intervention, regardless of verified efficacy, will be constrained by barriers around initial or continuous engagement. This point might be especially germane to instances where training is directed towards a depressive presentation, where depleted motivation is a recognised symptom (B. Smith, 2013). Further, this point is clearly circular in nature, as individual motivation to engage will additionally likely depend on anticipated profit, which subsequently reintroduces the concern around control and response-bias effects.

At this point it seems necessary to consider an alternative account for the lack of consistency in findings, which signals more to the potentially valid limitations of CBM. Blackwell et al. (2015) reported more pronounced between-group differences when historic episodes of depression were controlled for; fewer than five previous episodes of depression resulted in larger between-group differences. Further, Salemink et al. (2009) found changes in interpretive biases contingent with training group only when they were measured immediately and within the same context. Although this contradicts research that has specifically explored this capacity (Mackintosh et al., 2006; Yiend et al., 2005), these results might represent a possibly weaker clinical potential for CBM. Alternatively, two studies

investigating the influence of CBM on depressive symptomology revealed findings that alluded to the training impacting specific but not general features of the presentation (e.g. anhedonia). This is complicated by the choice of measures employed in studies generally, which commonly favour global scores of symptomology and so may lack the sensitivity required to capture more precise changes. However, these combined findings may suggest that the clinical application of CBM training might be best suited to less entrenched difficulties, and so may hold more credibility as an option in primary care services.

Until the processes by which CBM operate are more thoroughly understood, there remains a critical importance of ensuring that future studies continue to incorporate measures that sensitively but accurately measure change in interpretive bias. Evidence for this comes from findings from Hoppitt et al. (2014) and Salemink et al. (2014), which revealed general rather than targeted improvements in interpretive bias. This observation was facilitated by features of the bias measurement tool, the Ambiguous Scenarios Test, which allowed for differences between foil (general positive/negative items) and target (topics relating specifically to the training focus) to be statistically explored. This level of regulation is not afforded in studies that used the SST that instead provides a single negativity score, and represents a design limitation to such research.

An additional variation that is featured in the included studies relates to the delivery mode of training. Studies included in this review that explored the utility of CBM as an intervention for depressive symptomology presented training auditorily, while those investigating the impact on anxiety presented scenarios on-screen for participants to read through. The former has been argued to aid more visual processing of the material, involving the use of imagery, which has been identified as particularly necessary for individuals with depression (Holmes, Lang, & Shah, 2009; Wesslau, Cloos, Höfling, & Steil, 2015). However, this presentation technique requires a passive involvement with the resolution of ambiguity

compared to traditional methods in which participants are required to actively resolve word fragments at the end of each scenario. This feature of the training requires further exploration alongside having an advanced understanding around the optimal number of training sessions, differences between gender and age receptivity, and a better understanding of the varying suitability of CBM for different clinical presentations.

Four studies in this review explore the efficacy of CBM alongside an established treatment intervention (cCBT). While this is a necessary and justified design given the purported potential for CBM to supplement current interventions (e.g. Beard, 2011; Brosan, Hoppitt, Shelfer, Sillence, & Mackintosh, 2011), it obscures the clarity with which it is possible to isolate CBM-specific effects in research. This is considered to be an unintentional artefact of reviewing studies that capture the intermediate stage of transition to clinical application but, nonetheless, a shortcoming of the present review.

This review is further limited by the confines of inclusion criteria, meaning that only studies published in English peer-reviewed journals were included. While the search process entailed checking through the citations of included studies for overlooked research, it is not possible to confidently state that all relevant studies were captured within this review. It is also recognised that null findings can prove more difficult to publish, which can unintentionally threaten the credibility of reviews such as this and, more critically, the clinical practice that evidence informs (Kepes, Banks, & Oh, 2014). The review intentionally focused on CBM training that employed a scenarios-based paradigm in an effort to manage confounding training-specificity differences. This constrains the generalisability of the conclusions drawn here to other home-based bias training research (e.g. Brettschneider, Neumann, Berger, Renneberg, & Boettcher, 2015). In addition, the inclusion of research that employs different study designs has complicated the task of impartially and uniformly assessing methodological quality. Reviews that compare findings between studies that adopt

consistent study designs are afforded an enhanced ability to evaluate study quality through the use of standardised quality assessment tools. As the review question addressed here pertained more to synthesising the current state of progress in an emerging field of research, it was necessary to set less restrictive limits around the homogeneity of study design. The application of Higgins and Green's (2011) broad quality criteria therefore offered some platform to consider methodological quality despite the differences in study design; albeit with reduced precision.

These limitations notwithstanding, the findings from this review are broadly consistent with other reviews of CBM for interpretive biases and, to the best of the author's knowledge, represents the first attempt to exclusively integrate findings specific to home-based CBM interventions.

1.5. Conclusions

Findings from 12 studies, that employed a range of research designs, allude to a moderate potential for home-based CBM interventions. This evidence appears most robust when targeting depressive compared to anxious symptomology, which might partially be explained in that studies of the former explored a single disorder enabling a more standardised sample. Few studies exhibited clear training effects on interpretive biases, however the range and sensitivity of bias tests used to measure this might account for these absent findings to some measure. Despite differences in precise training paradigms (e.g. mode of delivery, number of training sessions), the lack of an appropriate control group is argued here to have presented the most significant limitation common to all studies. This is compounded by the lack of understanding related to the precise nature by which CBM training effects occur, thereby increasing the complexity around understanding which features are important to hold constant and which to experimentally manipulate between

groups. As more research allows an improved understanding of this, future reviews might additionally be able to provide a clearer summary.

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Chapter 2. Bridging Section

The previous chapter provides evidence for the potential of CBM interventions in the home environment. However, the reviewed literature revealed a gap in our understanding as to how this training might differently influence individuals across the lifespan. Although few studies represented the younger stages of life, alternative research exists that explore the efficacy of CBM training in children and adolescents; albeit not using home-based packages (e.g. Lau, Molyneaux, Telma, Belli, 2011; Lothmann, Holmes, Chan, & Lau, 2011; Orchard, Apetroaia, Clarke, & Creswell, 2017; Vassilopoulos, Moberly, & Lau, 2015). In contrast, there is a distinct absence of research that aims to explore these issues in older adults.

Based on the evidence that older adults show equivalent response rates to psychological interventions compared to younger adults (Gonçalves & Byrne, 2012), current national guidance in clinical practice across England does not distinguish between recommended therapy based on age. Given that both CBM and more traditional psychological therapies similarly focus on biased information processing, it seems a reasonable conjecture that adults of different ages would show comparable response rates to the two methods. However, differences between the manner of engaging with either technique necessitates cause for specific exploration of this hypothesis. It is possible that older adults might show a poorer response to CBM owing to cognitive changes that occur across later life as part of the normal ageing process (Harada, Love, & Triebel, 2013). For example, many older adults experience changes to their attentional capacity (Kensinger, 2009), which might impede engagement and restrict beneficial gain. It remains in debate as to whether these changes occur directly due to organic (i.e. brain) alterations or reflect a by-product of alternative physical impairments (i.e. hearing or sight difficulties increasing the challenge of attending). Either way, the implication remains that these changes in attentional processing could significantly impact on the application of CBM with older adults. Arguably,

the reduced familiarity and typical use of technology in the current older age cohort (Selwyn, Gorard, Furlong, & Madden, 2003) might also deter practice. Alternatively, given the typical decline in physical mobility across later life (Vandervoort, 2002), home-based interventions, such as CBM, might offer a more convenient and suitable option for older adults; particularly in more rural areas of the country where access to transport might present additional barriers to seeking help. Clearly the issue warrants further attention, which forms the focus for the ensuing chapter.

**Chapter 3. Quantitative research paper prepared for submission to the Journal of
Anxiety Disorders**

The influence of interpretive cognitive bias modification on generalised anxiety in older adults

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Abstract

Threat-focused interpretation biases have been linked to the aetiology and maintenance of emotional disorders. Cognitive bias modification (CBM) is an experimental paradigm designed to retrain biases through repeatedly accessing exclusively positive interpretations of ambiguous stimuli. Consensus over the potential clinical utility of CBM remains unsettled, although there is scope for its use to augment current psychological interventions. Research seems focused on developing a CBM package for access in the community, however study samples lack appropriate representation across the lifespan. This study explored the efficacy of a home-based seven-day CBM package delivered to older adults who reported generalised anxiety symptomology. Using a single-case series design, six participants completed daily computerised training targeting interpretive biases around worry. Overall, half of the participants showed improvements in daily well-being measures in line with the study hypothesis. Statistically significant reductions were identified in collective scores on a diagnostic measure of generalised anxiety disorder, with the magnitude of change indicating reliable but not clinically meaningful improvements. No training effects were evident in interpretive bias, measured using a scrambled sentences task. These findings support the notion that CBM might offer some therapeutic value to older adults and are discussed in light of methodological limitations and previous research.

Keywords: interpretive bias; cognitive bias modification; generalised anxiety; GAD; older adults; elderly

3.1. Introduction

The association between the manner in which individuals process information and their emotional reactivity and well-being has been well established. When presented with ambiguous information, ‘healthy’ individuals typically show a preference towards positive or neutral cues, while clinically anxious individuals tend to favour threat-related information (Eysenck, Mogg, May, Richards, & Mathews, 1991; Mathews & MacLeod, 2005). This pattern has been demonstrated both in the way that individuals attend to information (e.g. MacLeod, Mathews, & Tata, 1986), and how they interpret it (e.g. Mathews, Richards, & Eysenck, 1989); typically referred to as attentional and interpretive biases. Such biased information processing styles form the fundamental basis for theoretical conceptualisations around the aetiology and maintaining factors in emotional disorders. For example, generalised anxiety disorder (GAD) is characterised by pathological worry in which an individual enters repetitive cycles of catastrophic threat-related thinking. Hirsch and Mathews (2012) argue that attentional and interpretive biases operate in a manner that drives and maintains focus towards potential threat at both a pre-conscious and conscious level.

Cognitive bias modification (CBM) works on the assumption that inherent information processing biases can be retrained through experimental paradigms that constrain an individual’s interpretation of ambiguous information. By repeatedly accessing interpretations of ambiguous stimuli that exclusively represented either the positive or negative meaning, Grey and Mathews (2000) observed a training-congruent change in interpretive bias. Research has extended this finding by demonstrating that such training additionally leads to corresponding changes in analogue emotional pathology (Mathews & Mackintosh, 2000). These effects have since been shown to persist across time (Yiend, Mackintosh, & Mathews, 2005) and increase emotional resilience to future stress (Mackintosh, Mathews, Yiend, Ridgeway & Cook, 2006; Wilson, MacLeod, Mathews, &

Rutherford, 2006), both in clinical and non-clinical populations (Hayes, Hirsch, Krebs, & Mathews, 2010; Hirsch, Hayes, & Mathews, 2009).

Since its inception, research has focused towards exploring the potential clinical utility of CBM paradigms. As the training is traditionally delivered electronically, CBM packages offer a psychologically-based intervention that is low in resource demand compared to standard psychotherapies. While several meta-analytic reviews have cautioned a limited clinical potential for CBM (e.g. Cristea, Kok, & Cuijpers, 2015; Hallion & Ruscio, 2011; Menne-Lothmann et al., 2014), research continues to explore ways that the technique might ultimately augment current approaches (e.g. Brosan, Hoppitt, Shelfer, Sillence, & Mackintosh, 2011). One such option for this is through developing a home-based training package that might be offered to individuals as a standard prerequisite to psychotherapy or waitlist option. Recent efforts that are focused more towards identifying the extent to which CBM is effective in more naturalistic environments have produced mixed findings (e.g. Blackwell & Holmes, 2010; Salemink, Kindt, Rienties, & van den Hout, 2014; Williams et al., 2015). However, to date no published study has focused on exploring home-based CBM packages in individuals suffering from generalised anxiety symptomology. This could be useful given that people who experience anxiety disorders will often avoid seeking professional help as a consequence of their anxiety; particularly older adults (Mackenzie, Reynolds, Cairney, Streiner, & Sareen, 2012). This latter point reflects a more significant and global shortcoming for all CBM research thus far, in that study samples have tended to feature disproportionate age ranges with older adult populations being consistently under-represented. For example, using data from the 20 studies that reported such information in Menne-Lothmann et al.'s (2014) meta-analysis, the overall mean age can be calculated at 26.5 years old ($SD = 9.6$ years). This limits our understanding of the degree to which the effects of CBM are seen across the lifespan.

As the only current published study to explore CBM in an older adult population, Murphy et al. (2015) failed to identify any training-specific differences on interpretive bias or depressive or anxiety-based symptomology. Participants showed global improvements in well-being measures regardless of whether they received 12 sessions of positive CBM for interpretation or a control variant in which ambiguity was resolved equally in a positive and threat-focused manner. However, all training was delivered at a research facility, therefore these improvements might have reflected the high degree of direct contact and support that participants necessarily received. Nevertheless, the study speaks encouragingly to the acceptability and potential for computerised therapeutic packages more generally to be applicable to the current older adult cohort. This is further supported by recent research that has explored such issues using computerised forms of self-guided cognitive behavioural therapy (Dear et al., 2015; Titov et al., 2015).

In an effort to bridge the gap in current understanding around the clinical utility of CBM for interpretation, the present study aims to explore the effectiveness of a home-based worry-focused interpretive CBM package in older adults with generalised anxiety symptomology. Owing to the lack of data available around likely uptake and acceptability of CBM training in an older adult population, a single case experimental design was adopted as an appropriate method to collect information that might guide future research exploring this. Based on previous findings, it was hypothesised that the completion of a week-long daily CBM training package would lead to improvements in interpretive bias and corresponding reductions in reported GAD symptoms.

3.2. Material and Methods

3.2.1. Design

Single case experimental design allows for the intensive study of target variables at an individual level across phases. Within any field of investigation, this methodology can complement findings from larger scale study designs, such as randomised controlled trials, to give a more comprehensive understanding of both the broad and more concentrated patterns of response (e.g. Fox, Mackintosh, & Holmes, 2014). A non-concurrent multiple baseline single case design (Watson & Workman, 1981) with follow-up was employed here (see Figure 3.1). The provision of multiple baseline lengths affords a level of control over study acclimatisation, and is designed to increase the confidence with which changes in the target variable can be attributed to particular phases of the study (Macgowan & Wong, 2014). Participants were randomly assigned to predetermined baseline phases (7, 9, or 11 days in length) using an online random algorithm generator ([RANDOM.ORG](https://www.random.org)). Following this, all participants completed a seven-day home-based CBM training phase. Participants then completed a seven-day follow-up phase to monitor immediate post-intervention change. During all phases, participants completed daily measures of anxiety, mood, and anxiety-related bias.

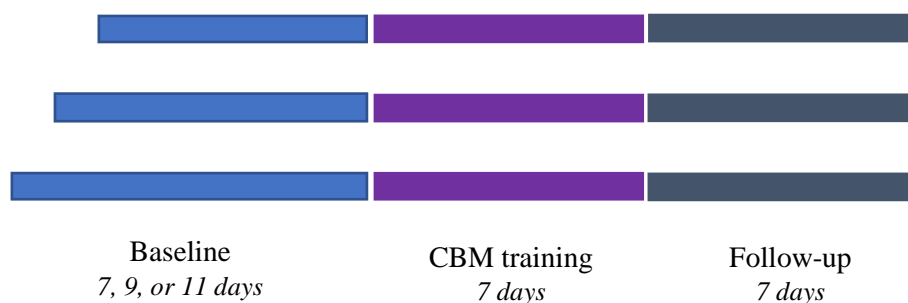


Figure 3.1. Phases of non-concurrent multiple baseline single case design

3.2.2. Participants

Individuals were recruited from across East Anglia, England, through primary and secondary care mental health services, and voluntary and third sector local organisations. Inclusion criteria required individuals to be 60 years old or above and report struggling with worry or general anxiety as their primary difficulty. Exclusion criteria included the presence of current severe co-morbid mental or physical health difficulties (e.g. current episode of severe depression or mania; current florid psychosis; current substance abuse), any form of cognitive impairment, or being in current receipt of psychological interventions. Eligibility status was confirmed through a screening process (see section 3.4 for further information). Of the 30 individuals that were initially identified as potentially suitable, 10 people consented to be screened for the study and were considered eligible to participate. Six participants provided full data sets for analysis (participants three and nine, both female, withdrew during the baseline phase due to physical ill-health; data from participant four, also female, was removed following non-completion of CBM training, and participant ten, male, withdrew during the baseline phase). The mean final sample age for the six participants whose data was analysed was 75 years old ($SD = 5.74$), and included two females (participants two and five).

3.2.3. CBM Training

All training content was hosted through E-Prime 2.0 software (Pittsburgh, PA: Psychology Software Tools) presented on the screen of a laptop (Toshiba Satellite Pro; Windows 10 operating system), which participants were loaned. Scenarios were automatically presented one line at a time according to pre-set timings, although participants could manually accelerate delivery of training content where preferred.

At the beginning of each daily training, participants read through reminder instructions informing them of the purpose and conduct of the training. The

comprehensiveness of these instructions was tailored to progress throughout the training phase, with briefer instructions being provided towards the end of this phase. Contained within these instructions was specific information around the importance of and guidance as to how to adopt a field perspective when imagining themselves within each scenario, even when they deemed the topic as irrelevant to them. Participants completed a daily imagery exercise followed by a practice scenario containing non-emotive content prior to commencing the training items to refamiliarize and prepare them for the training ahead.

Daily CBM training was comprised of 50 ambiguous scenarios (five blocks of 10 scenarios) that consistently resolved into a positive or neutral interpretation on completion of a word fragment placed at the end of each paragraph. For example, *'As a member of a local charity, you are asked to promote your fund-raising events on local radio the following week. You know that the station is widely listened to and expect that the other committee members will think you spoke convincingly'* [convincingly]. Participants were required to indicate when they have recognised the word, and then to press the letter key corresponding to the first missing letter (e.g. the letter *i* in the above scenario). Following this, participants were presented with a simple comprehension question to reinforce the valence of the resolved meaning. For example, *'Do you think your committee members thought you were a poor speaker?'* [No]. Following each training block, participants were asked to rate the extent to which they had successfully managed to generate clear mental images for the preceding scenarios, and indicate this on a 10-point scale. Blocks of CBM training items were separated by an optional short comfort break.

Each day featured new training items, resulting in 350 scenarios being covered over the seven days. Two set presentation orders for scenarios were devised using an online random sequence generator ([RANDOM.ORG](https://www.random.org)), and participants were assigned to either sequence according to a counter-balanced predetermined algorithm generated from that same

software. Scenarios were taken from McNally (2014), with 183 (52%) being partially or fully revised to ensure that the topic remained relevant for the current sample. Finalised scenario items were checked for content and accuracy by a member of the research team with a clinical background in working with older adults.

3.2.4. Outcome Measures

3.2.4.1. Generalised anxiety disorder questionnaire-IV (GAD-Q-IV; Newman et al, 2002). The GAD-Q-IV was used as a screening tool to identify clinical levels of generalised anxiety, and as a primary outcome measure to quantify clinically meaningful and reliable change over time. The measure was originally devised as a diagnostic self-report tool for generalised anxiety disorder (GAD) based on clinical criteria listed in the Diagnostic and Statistical Manual of Mental Disorders (4th ed; DSM-IV-TR; American Psychiatric Association, 2000). The criteria for GAD has remained unchanged in the updated DSM-5 (American Psychiatric Association, 2013). The measure has been shown to demonstrate good discriminant sensitivity and psychometric properties (Newman et al., 2002) in young adult populations. Revised cut-off scores (3.71 rather than the traditional 5.7) have been recommended when using the measure as a research screening tool in a community-based older adult population (Staples & Mohlman, 2012), which was implemented in the current study.

3.2.4.2. Scrambled sentences test (SST; Wenzlaff, 1993). The SST was used as a primary outcome measure of interpretive bias. Completion of the SST involves repeatedly reordering word strings to form coherent sentences. Each word string consists of six words, and can be reorganised using five of the words (one always remains unused) into either a positive/neutral or a threat-related sentence. For example, the word string '*appear to sensible I foolish others*' can be unscrambled to either read '*I appear sensible to others*' (positive

variant) or '*I appear foolish to others*' (threat-related variant). A negativity percentage score is calculated according to the ratio of negative and positive sentences that are formed from 20 word strings.

Participants completed the SST on three occasions, with word strings drawn from a pool of 80 items. These were taken from McNally (2014), with 15% of items being revised to ensure they remained relevant to the current study sample. Finalised word strings, and their associated interpretations, were checked by the same member of the research team (a clinician working with older adults) for accuracy and content validity. Each participant completed 60 of the 80 potential SST word strings (20 per occasion), the specific items and presentation of which were randomly selected on an individual basis using an online random sequence generator ([RANDOM.ORG](https://www.random.org)).

Previous studies that have utilised the SST (e.g. Blackwell & Holmes, 2010; McNally, 2014), have included a time-limit of four minutes and additional cognitive load (remembering a six-digit number; Bowler et al., 2012). The additional cognitive load condition was applied here with the exception of participant eight (due to very high anxiety levels), however the timed element was loosened. This was primarily because the SST was not completed in a research facility meaning that the timing element could not be consistently controlled across participants. Participants were instead instructed to give themselves “approximately five minutes” to complete the exercise as this was anticipated to retain the element of pressure that is proposed to deter individuals from consciously overriding their instinctive interpretation (Bowler et al., 2012).

3.2.5. Daily Measures

The standard formats of both the PHQ-9 and the GAD-7 (described below) enquire about the presence of symptomology over the preceding two weeks. As these measures were

here applied as daily measures of mood and anxiety, participants were instructed to answer items based on their experiences over the previous 24 hours.

3.2.5.1. Patient health questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a brief nine-item measure of depressive symptomology based on the DSM-IV criteria for major depressive disorder. These criteria have remained unchanged in the updated DSM 5. The measure has demonstrated good psychometric properties (Kroenke, Spitzer, Williams, & Löwe, 2010), and has been recommended as an appropriate measure of depressive symptomology in older adult populations (Phelan et al., 2010). Aggregate scores can be classified into categories of depression severity, with a score of 10 or above (indicating moderate depression; Kroenke et al., 2001) frequently being applied in research as a clinical threshold. As well as providing a daily measure of depressive symptomology, the PHQ-9 was used as a study screening tool with a score above 20 (indicating severe depression; Kroenke et al., 2001) set as an exclusion criteria.

3.2.5.2. Generalised anxiety disorder scale (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 is a brief seven-item measure of anxiety symptomology that demonstrates good psychometric properties in general and older adult populations (Spitzer et al., 2006; Wild et al., 2014). Scores give an indication of anxiety severity, with scores of 10 or above indicating moderate anxiety (Spitzer et al., 2006). In clinical practice within the United Kingdom, a lower clinical threshold of eight is typically adopted (Clark et al., 2009; Kendrick et al., 2009).

3.2.5.3. Visual analogue scales (VAS). Biased tendencies to worry or catastrophise were monitored using daily visual analogue scales. Participants were asked to indicate their subjective tendency to worry and “expect the worse” over the preceding 24 hours, which was achieved by placing a mark along a 10cm line with one terminal labelled *Not at all* and the

other labelled *All the time/Extremely* (respectively). The use of VAS has been similarly adopted in previous relevant research (e.g. Blackwell & Holmes, 2010; McNally, 2014).

3.2.6. Additional Measure

3.2.6.1. Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005). The MoCA is an easily administered clinical screening tool for cognitive impairment. The measure briefly tests respondents' short-term memory, visuospatial ability, executive functioning, attention, language skills, and orientation to provide an overall score of cognitive functioning. Despite its rapid administration, the MoCA has been shown to effect superior discriminant potential to competitive cognitive tests (Ciesielska et al., 2016), and demonstrates good psychometric properties (Nasreddine et al., 2005). For the present study, the MoCA was employed as a screening tool to verify levels of cognitive functioning. A cut-off of 26 (out of a possible 30) was set, as is the standard threshold indicating typical functioning (Nasreddine et al., 2005).

3.2.7. Procedure

This study was reviewed by a service-user representative panel, and ethical approval was granted through the Health Research Authority's proportionate review system. It was then promoted to Trust-wide primary and secondary care mental health services, who subsequently referred potentially suitable individuals who were interested in participating. The study was also promoted through non-NHS local organisations where individuals could self-refer if they identified with the listed inclusion/exclusion criteria. All phases of study participation were completed within the participant's own environment.

Following a telephone conversation to screen for obvious ineligibility, an appointment was arranged for a home-visit from a member of the research team to consent individuals into the study and complete the screening measures (GAD-Q-IV; PHQ-9; MoCA). Assuming

eligibility status was confirmed, participants were then provided with a questionnaire pack consisting of the daily measures, and a personalised study calendar detailing their start date and the transitions into different phases of the study. Participants proceeded to complete the daily well-being measures at home during the baseline phase (7, 9, or 11 days depending on their random assignment). At the end of this phase, participants were visited at their home to be introduced to the SST (which was first completed on participants' final baseline day) and receive training on the CBM computer programme. This training included familiarisation and instruction on how to use the laptop (tailored to prior individual experience), and a rehearsal of how to access and complete the daily training. Participants were provided with comprehensive as well as brief paper instructions and a diagram of the laptop keyboard to serve as reminders. Over the course of the seven-day training phase, participants completed their daily well-being measures and the corresponding daily training (these were organised and labelled accordingly on the desktop of the laptop). For seven ensuing days, participants continued to complete daily well-being measures, and additionally completed the SST on the first and final day of this follow-up phase. Participants were then visited again at home to debrief, where they were also presented with a £15 shopping voucher as a token of appreciation.

While participants were only visited on three occasions at home, they could contact the research team by phone for support where it was required. This was initially left to individual discretion, however the procedure was iteratively amended to include a 'check-in' phone call as a set minimum contact at the beginning of the CBM training phase to troubleshoot any experienced difficulties. This followed one participant (participant four) not completing the CBM training due to their concern over using the laptop. In this instance, no contact was made to the research team, and the participant's data was necessarily removed from the analysis process.

3.2.8 Analysis Plan

Kendall's *tau* analysis will be conducted on all measures of individuals' baseline phase to identify stability in self-reported symptomology. Individual data from the daily well-being measures will then graphically represented, and subjected to a visual inspection analysis to identify any change across time consistent with the varying phases of the study (Barlow & Hersen, 1984). Specific focus will be given to the rate and magnitude of any observed change (Kazdin, 2011). Where average daily scores showed hypothesis-consistent improvements between the baseline and CBM training phases of the study, individuals will be classified as a *responder*; otherwise they were deemed a *non-responder*.

To support the subjective interpretation of data trends, the Jacobson-Truax (1991) methodology of determining clinical and reliable change will then be applied to GAD-Q-IV data. Further statistical analyses, in the form of Wilcoxon signed-ranks tests, will also be conducted to determine change in primary outcome measures (GAD-Q-IV and SST scores).

3.3. Results

3.3.1. Visual Inspection

3.3.1.1. Participant one; male, 75 years old. Average reported depressive and generalised anxiety symptomology appeared lower during the training phase compared to baseline (Figure 3.2), however both phases were characterised by a pattern indicating an initial worsening and subsequent improvement in state across the course of the phase. Kendall's *tau* confirmed significant variability in GAD-7 scores across the baseline phase ($\tau = -0.74, p = 0.01$), however baseline stability was established in PHQ-9 data ($\tau = -0.40, p = 0.14$). In both measures, improvements appeared to stabilise towards the end of the training phase, which appeared to be maintained across the follow-up phase. Significant variability was identified in scores on both VAS measures during the baseline phase

(VASworry: $\tau = -0.65$, $p = 0.02$; VAScatastrophise: $\tau = -0.56$, $p = 0.04$). Otherwise, patterns of VAS reporting and average data across each phase of the study appeared similar to the PHQ-9 and GAD-7 measures (Figure 3.2). Participant one was classified as a *responder*.

3.3.1.2. Participant two; female, 78 years old. Kendall's τ analyses revealed significant variability across all baseline measures (PHQ-9: $\tau = -0.70$, $p = 0.01$; GAD-7: $\tau = -0.89$, $p < 0.001$; VASworry: $\tau = -0.94$, $p < 0.001$; VAScatastrophise: $\tau = -0.95$, $p < 0.001$). Figure 3.2 suggests a pattern of response in which improvements seem to occur throughout the baseline phase. No clear change in mean symptomology is evident following this phase. Participant two is classified as a *non-responder*.

3.3.1.3. Participant five⁶; female, 67 years old. Stability across the baseline phase was established for all outcome measures (PHQ-9: $\tau = 0.44$, $p = 0.11$; GAD-7: $\tau = 0.51$, $p = 0.07$; VASworry: $\tau = -0.42$, $p = 0.12$; VAScatastrophise: $\tau = -0.47$, $p = 0.12$). For the PHQ-9, GAD-7, and VASworry measures, average scores appear lower in the training phase compared to the baseline phase, which seems to be consolidated across the follow-up phase (Figure 3.2). For the VAScatastrophise data, a floor effect is evident in which the measure is never properly endorsed. Participant five is classified as a *responder*.

⁶ Data from participants three, four, nine, and ten are not reported here; see section 3.1 for more details.

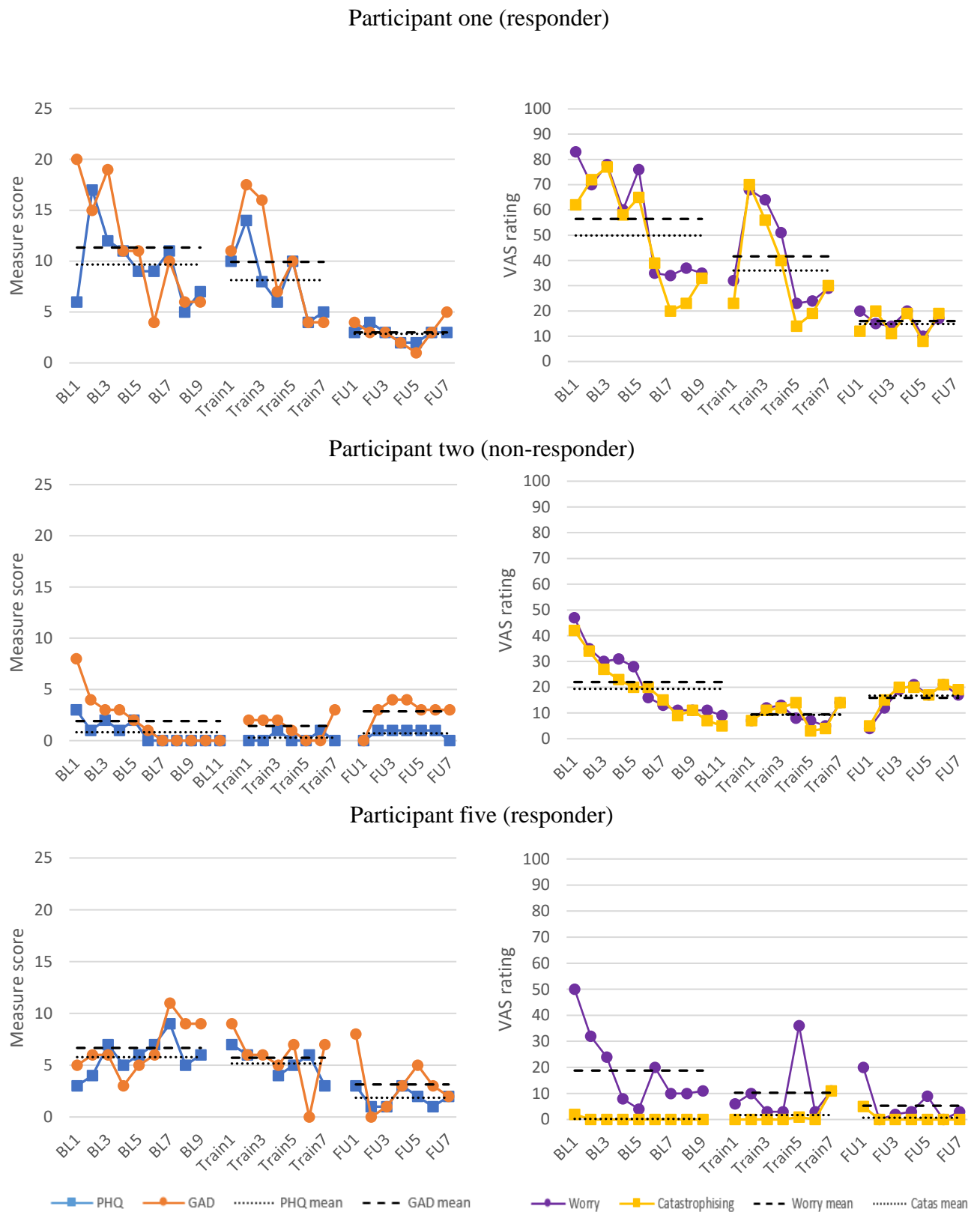


Figure 3.2. Participants' reported symptomology across the study

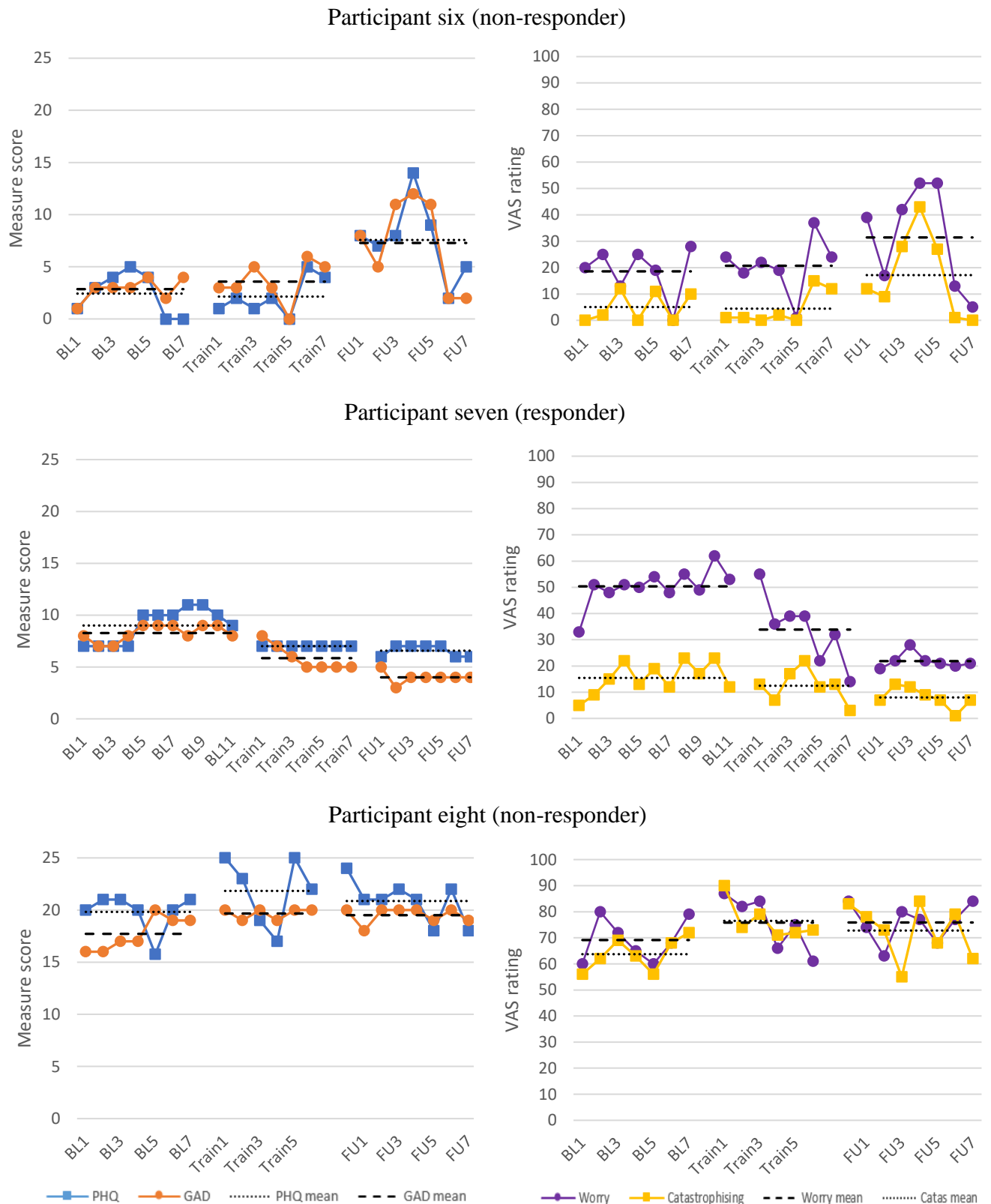


Figure 3.2. (Continued)

3.3.1.4. Participant six; male, 70 years old. Stability across the baseline phase was established for all outcome measures (PHQ-9: $\tau = -0.15$, $p = 0.65$; GAD-7: $\tau = 0.48$, $p = 0.15$; VASworry: $\tau = 0$, $p = 1.0$; VAScatastrophise: $\tau = 0.10$, $p = 0.75$). While similar variation and mean scores appear evident across the baseline and training study phases, the follow-up phase is characterised by a temporary deterioration across all measures followed by a return to prior levels (Figure 3.2). As a result, overall mean scores indicate an overall worsening in symptomology in the follow-up stage. Participant six is classified as a *non-responder*.

3.3.1.5. Participant seven; male, 75 years old. Kendall's τ analyses revealed significant variation in PHQ-9 scores across the baseline phase ($\tau = 0.54$, $p = 0.03$), while all other measures were found to be stable across this stage (GAD-7: $\tau = 0.39$, $p = 0.13$; VASworry: $\tau = 0.43$, $p = 0.07$; VAScatastrophise: $\tau = 0.35$, $p = 0.14$). Figure 3.2 suggests that PHQ-9 scores reflect an improved and more stable pattern across the training and follow-up phases. Clear reductions across the training phase are evident for GAD-7 and VASworry scores, which are maintained across the follow-up. Little change in response is noticeable on VAScatastrophise scores. Participant seven is classified as a *responder*.

3.3.1.6. Participant eight; male, 85 years old. Kendall's τ analyses revealed significant variation in GAD-7 scores across the baseline phase ($\tau = 0.72$, $p = 0.03$), while all other measures were found to be stable across this stage (PHQ-9: $\tau = -0.06$, $p = 0.87$; VASworry: $\tau = 0.10$, $p = 0.76$; VAScatastrophise: $\tau = 0.88$, $p = 0.13$). Figure 3.2 shows a consistent pattern of high symptomology in all measures across each of the study phases. Average data patterns across stage suggest that these are lowest during the baseline phase of the study. Participant eight is classified as a *non-responder*.

3.3.2. Reliable and Clinical Change

Using the Jacobson-Truax methodology (Jacobson & Truax, 1991), a reliable change index (RCI) of 3.40 was calculated for the GAD-Q-IV utilising normative data provided in Staples and Mohlman (2012). Clinically significant change was judged to have occurred where participants' follow-up GAD-Q-IV scores fell below the clinical cut-off (3.71) suggested by Staples and Mohlman (2012). In accordance with Wise (2004), participants were deemed to be *recovered* if both reliable and clinical change was identified, *improved* if success was evident in only one index, and *unchanged* in situations where neither was ascertained. Figure 3.3 reveals that participants one and seven achieved *recovered* status, participants two, five, and six showed an *improved* status, and participant eight remained *unchanged*.

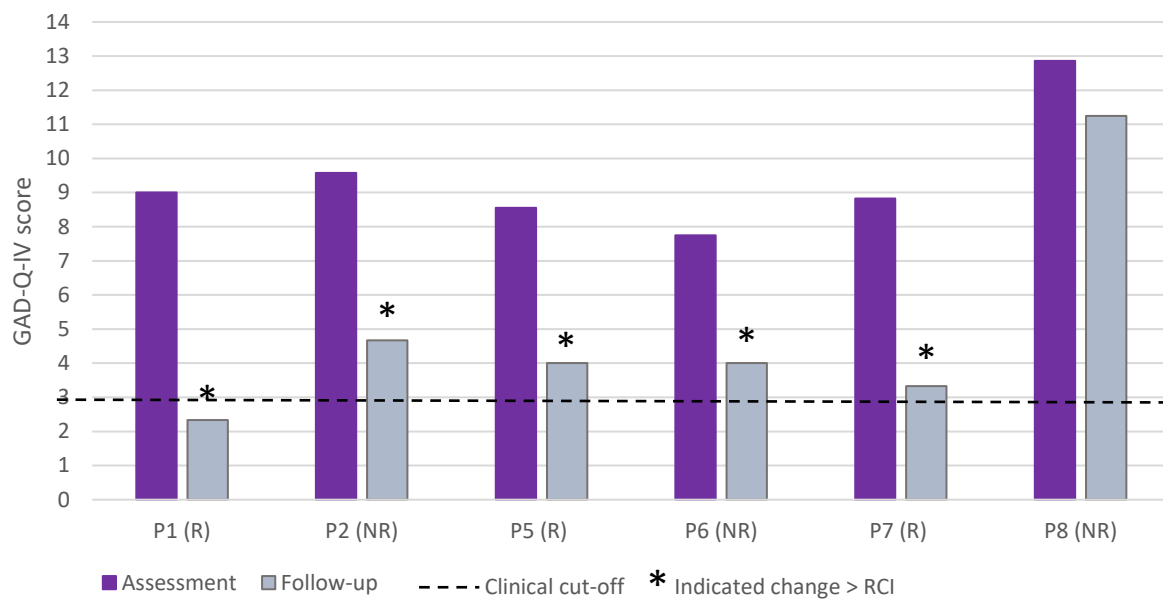


Figure 3.3. Reliable and significant change on GAD-Q-IV measure

3.3.3. Statistical Analysis and Effect Size

A Wilcoxon signed-ranks test was conducted on mean GAD-Q-IV data measured at the screening assessment and at the end of the follow-up stage. An overall significant decrease emerged ($z = -2.20$, $p = 0.03$, $r = -0.64$) from an average of 9.43 ($SD = 1.78$) to 4.93

($SD = 3.2$). This aggregate decrease suggests an overall reliable change, however the follow-up mean was maintained above the clinically significant cut-off.

Wilcoxon signed-ranks tests were conducted on SST scores comparing pre-training to post-training, post-training to follow-up, and pre-training to follow-up (Figure 3.4).

Participants six and seven achieved negativity scores of zero, which was considered to be an unrepresentative measure of their interpretive bias⁷. Due to these concerns around data validity, data from participants six and seven were excluded from further analysis. No analyses revealed significant change, although a trend decrease in scores emerged between pre-training to follow-up ($z = -1.83$, $p = 0.07$, $r = -0.65$) from an average negativity score of 39% ($SD = 11$) to 25% ($SD = 6$)⁸.

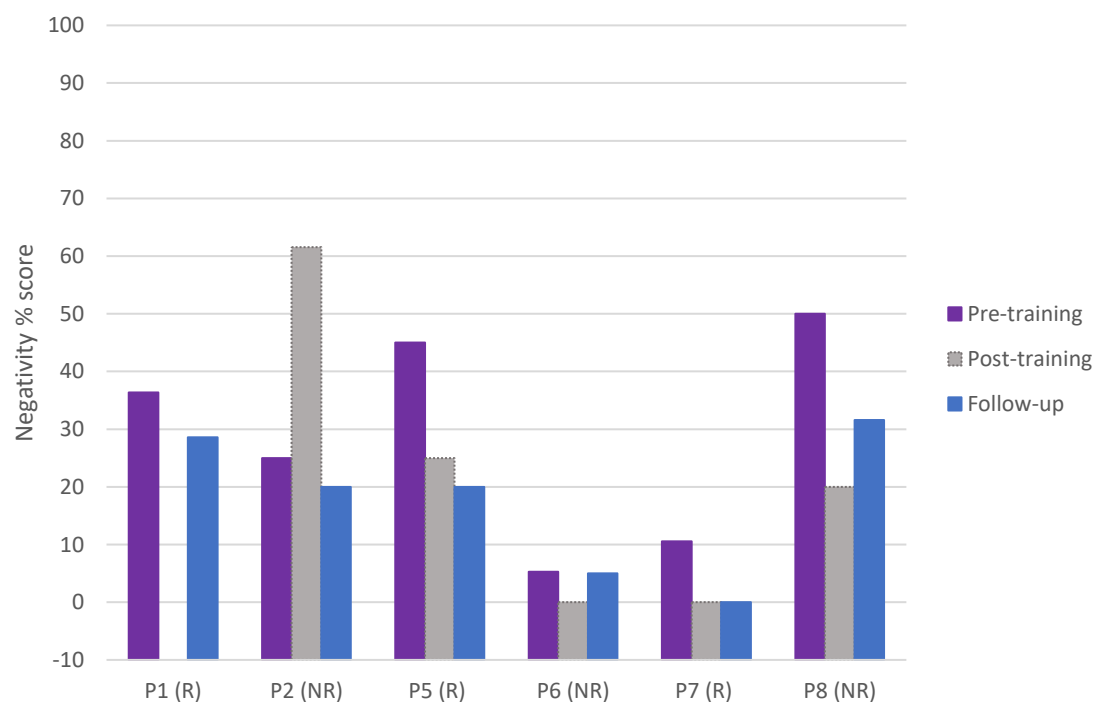


Figure 3.4. Changes in participant interpretive bias across time⁹

⁷ This hypothesis is supported by qualitative feedback given by participants six and seven, in which they reported effortfully trying to avoid constructing a negative sentence.

⁸ No differences in significance emerged when data from participants six and seven were included, although the trend analysis did achieve statistical significance ($p = 0.04$).

⁹ No data was available for participant one's post-training SST due to an administration error. Labelling of X axis starts at -10 to reflect the genuine zero scores of participants six and seven (not to be confused with absence of score).

3.4. Discussion

The present study aimed to investigate the efficacy of a home-based CBM training package targeting generalised anxiety symptomology in an older adult population. The findings generate some support for the research hypothesis with evidence of a mixed response to training on emotional pathology. Half of participants were classified as *responders* due to the observation that CBM training appeared to bring about positive changes in daily measures of well-being. Alternatively, half were classified as *non-responders* following no identified training-specific change or change reflecting a deterioration in symptomology. Variation in scores on the GAD-Q-IV, which specifically measures symptomology associated with the DSM-IV diagnostic criteria for generalised anxiety disorder, indicated that most participants showed some level of improvement across time. Two participants (one and seven) met criteria for *recovered* status, evidenced by reliable and clinically meaningful change; that is, their reduction in reported symptomology moved them closer to a normative mean for matched adults (reliable change) and their final score was below the measure-specific clinical threshold (clinical change). Three other participants achieved an *improved* status, characterised by reliable but not clinically meaningful change (i.e. their final scores remained above clinical threshold), while one participant (participant eight) was classified as *unchanged*, with GAD-Q-IV scores indicating neither reliable nor clinical change. As predicted, a statistically significant decrease in collective GAD-Q-IV scores was found, supported by a large effect size. The variation in aggregate group scores suggested a reliable but not clinically meaningful change. Contrary to the research hypothesis, however, no statistically significant change was found for group SST scores (measuring interpretive bias), although a trend decrease was observed between pre-training and follow-up scores.

The current pattern of findings is comparable to those reported by Blackwell and Holmes (2010), who similarly used a single case experimental design to investigate the effect of home-based CBM training on depressive symptomology in an adult population. They additionally documented a moderate response rate and likewise large effect size, however it is important to note that the within-subjects design of both studies means that these effect sizes are uncontrolled and, thus, are more susceptible to threats of internal validity (Butler, Chapman, Forman, & Beck, 2006). The findings similarly do not contradict Murphy et al.'s (2015) study that explored the influence of an affect-focused CBM training package in older adults. As previously mentioned, Murphy et al. (2015) identified positive changes in both the experimental (positive CBM) and control (equal positive/negative) groups, and no change in interpretive bias (similarly measured using the SST).

It remains difficult to draw confident parallels between the current study findings and those from previous CBM research owing to necessary differences in data analysis that result from the varying designs adopted to explore this. For the present study, individual data is explored independently and, while overall sample response patterns are statistically explored, there is no non-intervention group to compare these against. Nevertheless, the current response rate is not starkly different to recent meta-analytic findings indicating that one in every two older adult patients with GAD benefit from cognitive behavioural therapy (Hall, Kellet, Berrios, Bains, & Scott, 2016). Given that CBT forms the current recommended evidence-based approach alongside pharmaceutical management for GAD with marked functional impairment in the United Kingdom (National Institute for Health and Care Excellence, 2011), this finding is encouraging when considering the future clinical application of CBM.

The clinical threshold for the GAD-Q-IV utilised in the current study was set to 3.71 in line with Staples and Mohlman's (2012) recommendation for using the measure as a screen

for GAD in older adults. This is lower than the original 5.7 threshold suggested by the measure's authors, and increases the risk of false positive reporting (Newman et al., 2002). However, given that the measure was presently used to provide a clinical indication of GAD rather than to assign diagnostic labels, this concern holds less validity here. Coincidentally, all baseline GAD-Q-IV scores exceeded the 5.7 threshold, therefore the use of this lower limit arguably has here only actually led a more conservative estimate of clinical change being applied. From observing follow-up GAD-Q-IV scores, it is possible to determine that five of the six participants would have been deemed to have achieved clinically meaningful change had the original 5.7 cut-off been applied, rather than the identified two participants using the more conservative limit. In combination with their respective evidence of reliable change, such a difference would mean that all five achieved *recovered* status. However, when considered together with additional response patterns from other measures, this does not seem to accurately represent individuals' experiences through the study. For this reason, the findings from this study seem to support Staples and Mohlman's (2012) recommended lower clinical threshold as a more sensitive cut-off in research with an older adult population.

Despite the overall significant improvement in GAD-Q-IV scores, this study found no equivalent clear significant change in SST scores. This is somewhat surprising given the typical pattern for anxiety-based symptom improvements to be matched by improvements in interpretive bias (e.g. Butler et al., 2015; Hoppitt et al., 2014). However, variations in the method selected to measure interpretive bias might account for these between-study differences. Both Butler et al. (2015) and Hoppitt et al. (2014) employed a more traditional interpretive bias assessment; the Ambiguous Scenarios Test (Mathews & Mackintosh, 2000). This involves participants reading through a series of ambiguous scenarios, their recollection of which is later tested by rating the similarity of a series of statements for each scenario. Unknown to participants, these statements each contain two positive and two negative

interpretations of the original scenario, with each valence including a target (i.e. relevant) and a foil (i.e. generalised) possible interpretation. Inclusion of both foil and target items affords a level of control for individuals responding according to a generalised positive or negative bias, which is not offered through the SST. As such, when completing the SST, participants might exert conscious effort into avoiding constructing a sentence using the threat word. Such strategies would jeopardise data validity, meaning that overall negativity scores might not accurately represent an individual's biased interpretation style. This is argued to have occurred in the present study for participants six and seven (whose SST data was consequently excluded from analyses); both of whom achieved negativity scores of zero. This concern has not been documented in prior studies that have utilised the SST to measure interpretive bias (e.g. Lang, Blackwell, Harmer, Davison, & Holmes, 2012; McNally, 2014). Even so, future research might reasonably be recommended to use an interpretive bias test that affords more control to the measurement process, such as the Ambiguous Scenarios Test (Mathews & Mackintosh, 2000), to maximise sensitivity and validity boundaries. This is proposed to be particularly germane to instances where the clinical focus is known to feature elements of cognitive and behavioural avoidance, as is considered to be the case in generalised anxiety disorder (Newman & Llera, 2011).

The present findings are limited by the fact that stability across baseline was not established across all participants' daily well-being measures. This violates an assumption of the non-concurrent multiple baseline design (Watson & Workman, 1981) and, thus, reduces data credibility. Lane and Gast (2015) recommend increasing the length of baseline phases that feature variability until a clear period of stability is observed. This would require an iterative daily process of data analysis that was not feasible here due to the autonomous home-based nature of this research. This could be improved in future by offering online access to daily measures, which could then be monitored without the need for direct contact

with participants. The programming expertise required for this was not available for the present study. Further, engagement with technology was one issue being investigated here, therefore electronic delivery of questionnaires was considered less of a priority. Nevertheless, future replicability of these findings, along with further research into potential engagement barriers, are recommended prior to investigating efficacy in a larger scale trial.

An argued strength of the present study is in the committed exploration of CBM efficacy in a more naturalistic environment. Despite the fact that research into CBM has now been ongoing for nearly 20 years, studies are continuously designed in a way that involves participants completing CBM training sessions at research facilities (e.g. Beard et al., 2016). While this undoubtedly affords a stricter management of training compliance, thus yielding a higher level of confidence and certainty in data integrity, continued exploration of CBM potential exclusively within the safety of such an environment digresses from the argued purpose and value of independently-managed clinical CBM interventions. Engagement with any therapeutic technique is a key moderating factor in its efficacy, regardless of the demonstrated clinical potential. More research, therefore, needs to start exploring this principle to better understand and improve the realistic limitations that might threaten the clinical applicability of CBM both generally and with older adults. Encouragingly, there is evidence that this need is being responded to; for example, Krahé, Mathews, Whyte, and Hirsch (2016) recently published their randomised control trial protocol exploring home-based CBM training.

3.5. Conclusions

To the author's knowledge, this study represents the first attempt to explore the utility of anxiety-based CBM training exclusively in an older-adult population. Compared to other studies that have explored the utility of home-based CBM training for interpretive biases (e.g.

Salemink, Kindt, Rientes, & van den Hout, 2014; Salemink, van den Hout, & Kindt, 2009), and the aforementioned response rates to currently recommended treatment interventions, the present findings add weight to the argument that CBM training holds clinical potential and merits continued exploration. What remains clear at this point is the need for a more refined methodology to permit a clearer understanding of where absent or weak findings are due to study design fault and where they might reflect more genuine limitations around the clinical potential of CBM training; both for older adults with generalised anxiety symptoms, and other clinical presentations and populations.

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Chapter 4. Extended Methodology

4.1. Ethical Considerations

In recognition of the high time demand required for this study, efforts were made to maximise convenience for participants as much as possible while maintaining study rigour. All study appointments occurred within individuals' home environments, although participants were offered a neutral meeting place and also invited to have a family member or known person present for the first meeting. These arrangements were made to accommodate potential physical or mobility limitations that might otherwise prejudice an individual's ability to participate. Also with the aim of reducing participant burden, daily well-being measures were selected both for their scientific and clinical validity but also for their ease of completion.

A partial aim of the study involved exploring issues relating to engagement with and acceptability of a computerised CBM package in an older adult sample. For this reason, no inclusion criteria were specified relating to existing familiarity and confidence using computers. To reinforce this point, information relating to prior experience was not formally monitored or managed, however individuals were asked about this during the computer training to ensure that it was delivered to an appropriate level of depth. Half of the original 10 participants (participants two, five, six, seven, and ten) regularly used a computer, while the remaining participants (participants one, three, four, eight, and nine) reported limited or no prior experience.

4.2. Recruitment

The study was promoted to primary and secondary mental health services across the region through electronic means and attendance at directorate meetings, and to trainee clinicians on two training courses at the University of East Anglia via email. Brief

information relating to the study and referral process was additionally distributed on websites or through newsletters hosted by the NHS Trust research and development department and non-NHS local organisations. To protect individual confidentiality, recruitment into the study relied on referrals being offered from services or organisations already in contact with potentially appropriate individuals, or through self-referral. Despite initial registered interest from clinicians, actual referral rates into the study were low. The 10 individuals who were identified through this process originated from three sources; two individuals self-referred, one person from a specific NHS service, and the remaining seven from another.

4.3. Additional Study Measures

The following measures were additionally completed, but have been omitted from the empirical paper to afford a clearer focus throughout the article. Data from the below measures was analysed and is further discussed in Chapters 5 and 6 of this thesis.

4.3.1. CBM evaluation. To gain subjective feedback around the acceptability, ease of use, and perceived utility of CBM training, an evaluation measure was designed consisting of 10 VAS items and a space to provide qualitative feedback. This measure was anticipated to provide critical information relating to potential likely uptake of CBM training, which forms a key implementation issue. Participants were asked to complete this measure on their final (seventh) day of CBM training.

4.3.2. Subjective use of imagery scale (SUIS; Reisberg, Pearson, & Kosslyn, 2003). The SUIS requires respondents to indicate their tendency to utilise imagery in daily life by rating statements on a five-point Likert scale (*never appropriate* through to *always completely appropriate*) according to the extent to which it matches their own inclinations. Statements refer to specific situations, such as '*If I am looking for new furniture in a store, I always visualise what the furniture would look like in particular places in my home*'. In the

current study, the SUIS was administered during the screening assessment (although did not contribute to eligibility rulings), as subjective use of imagery has previously been suggested as a potential moderator of CBM efficacy (Blackwell & Holmes, 2010).

Chapter 5. Extended Analysis

5.1. CBM Data Extraction

Each time a participant completed the CBM training, a data file was produced that contained technical information relating to the running of the software and participant performance. For every response made during the running of the software, reaction time and raw response was recorded. This data was manually extracted for each participant to provide objective information relating to adherence to the training regime. Performance data was inspected as a likely indication of engagement with the training.

5.1.1. Adherence. Technical logging information captured time and date of CBM completion. This was cross-referenced with participants' individualised study calendars (detailing their scheduled training date) to verify training adherence. Participants two, five, and seven demonstrated 100% compliance with their scheduled training dates. Participant one and eight encountered technical difficulties and required telephone support during the CBM training phase. This resulted in them both missing one training session, with participant eight only managing to partially complete two additional training sessions (20% and 60% completion). Participant six completed all seven training sessions, however logging information recorded that six of these were completed consecutively on the same day. This was retrospectively checked with participant six's recollection of completing the training, who reported having to re-start one training session due to technical difficulties, but completing the others as per the scheduled timetable.

5.1.2. Performance. All participants demonstrated good accuracy in their ability to complete word fragments and answer the corresponding comprehension questions (see Figure 5.1). With the exception of participant five, individual accuracy scores for both areas of performance appear similar. This corresponded to subjective feedback given by participant

five (see section 5.2.2). Compared to other participants, participant eight appeared to show a moderate reduced overall accuracy in the completion both of word fragments and comprehension questions.

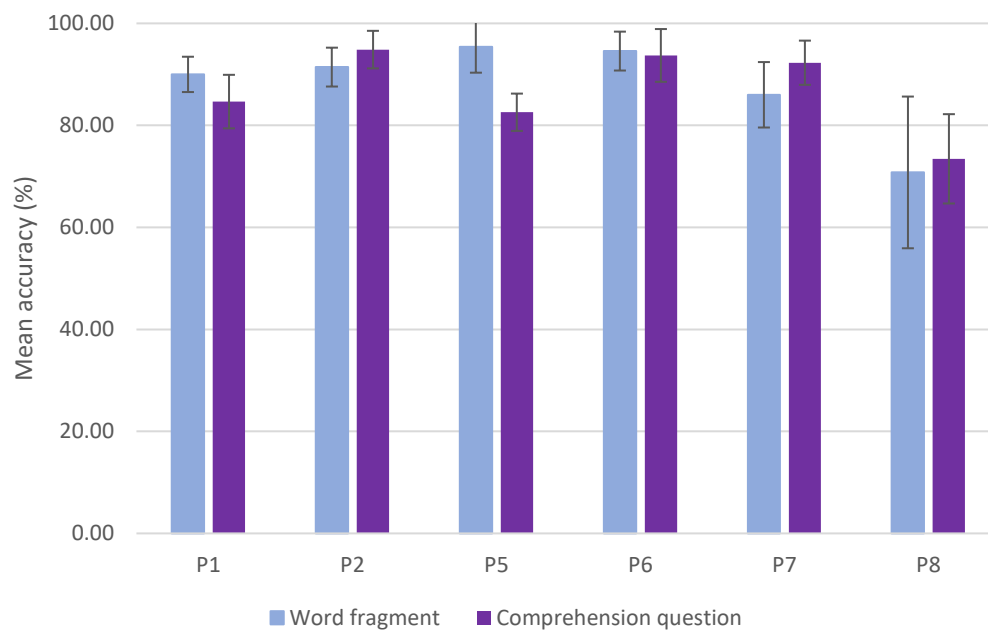


Figure 5.1. Mean CBM performance data

5.2. CBM Evaluation

Participants were invited to provide quantitative and qualitative feedback regarding the CBM training via the CBM evaluation measure. This was completed on the final training day to best capture individuals' accurate opinions, although opportunity to provide further qualitative feedback occurred during the debrief meeting with the researcher; held at the end of their participation.

5.2.1. Quantitative feedback. Quantitative ratings (see Figure 5.2) indicated a good level of acceptability around CBM, with high individual and collective ratings of factors related to the daily implementation of training. Subjective opinions relating to the efficacy of training indicated an overall moderate endorsement. Consensus in opinions around the use of computers to deliver the training seem less consistent. Given the clinical focus of this study

(generalised anxiety), ratings of initial concern around the use of computers is perhaps surprisingly low (an overall endorsement of 27%). This score is primarily composed of high individual ratings by two participants (one and eight), whose combined score represents 89% of the collective rating. Both individuals, as well as the overall group, indicated a decreased level of concern following the computer training session that occurred at the end of the baseline phase. Interestingly, neither of these participants indicated that the computer element of training would be a likely deterrent for other people in their age cohort. Alternatively, this latter score was predominantly composed by two other participants (five and six); neither of whom reported a large amount of initial subjective concerns themselves.

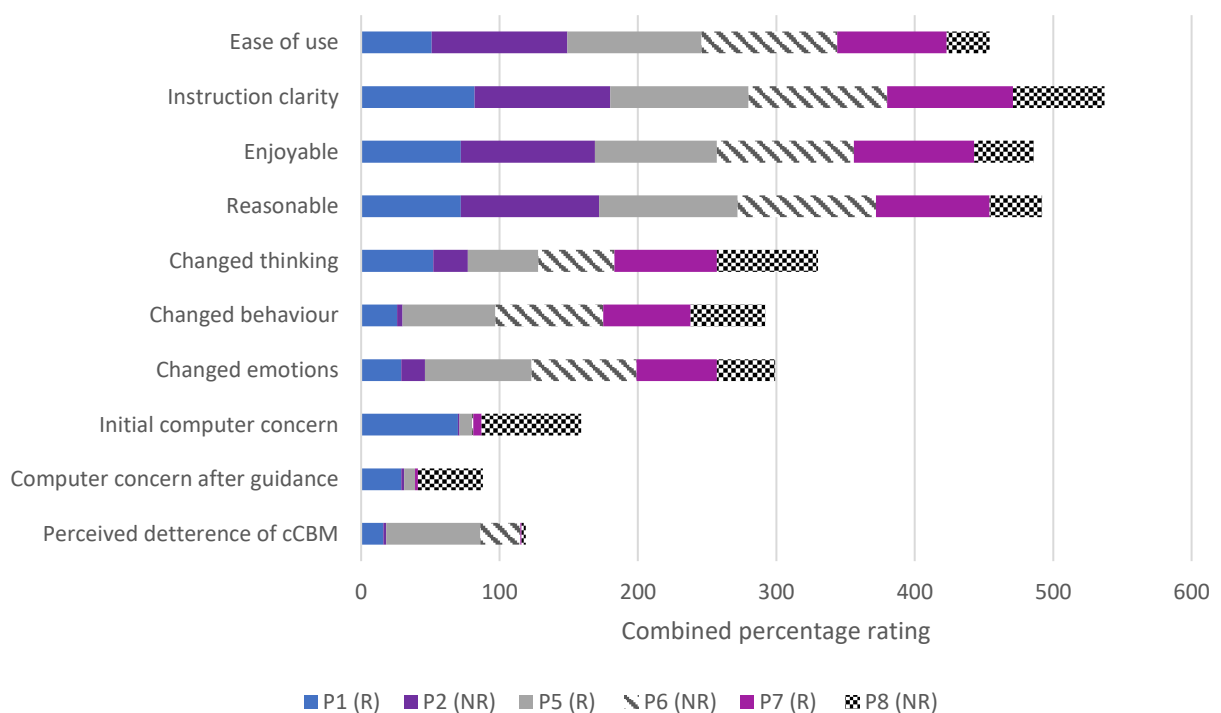


Figure 5.2. Participant quantitative feedback on CBM training

At this stage, it seems important to recall that only a third of individuals who appeared to meet study criteria consented to being contacted by the research team for formal study screening. Of the remaining two thirds, the involvement of a computer to access CBM training was consistently identified as the most common reason given for being deterred by

the study. No formal feedback or information relating to demographic factors of such individuals was collected, meaning it is not possible to further analyse underlying variables related to study deterrence.

5.2.2. Qualitative feedback and engagement. Together with quantitative ratings, participants' qualitative feedback provides a sense of how successfully different participants engaged with the training. For example, participant two reported becoming fixated on her ability to correctly and swiftly respond to the word fragments and comprehension questions. Her quantitative ratings suggested that the training was reasonably received in terms of how it was practically managed, yet of little subjective utility (identified through changes in thinking, emotional reactions, or behaviour). It is possible that participant two's focus on performance meant that she was less able to engage with the content of the training in a meaningful way. Similarly, participant five reported disliking the forced nature of the training (i.e. *having* to select the positive response to receive 'correct' feedback when answering comprehension questions). This is likely to account for her identified lower accuracy for comprehension questions. Participant six identified approaching both the SST and training as though it were a game; challenging himself to instantly identify and avoid using the threat-element contained within the SST statement or training. Despite this, participant six additionally identified that this process enabled him to develop his awareness of and try to regulate his habitual threat bias, which might account for the otherwise surprisingly high subjective perception of the training's utility. Finally, participant eight, who missed one full training session, only partially completed two others, and required a higher level of telephone support during the CBM training phase, reported finding the computer challenging to use. This is likely to have exacerbated his level of anxiety, thus reducing his ability to engage with the training fully. Such a hypothesis is supported by participant eight's performance data,

which indicates a higher number of errors in correctly responding to word fragments and comprehension questions.

5.3. Imagery

Mean SUIS scores and daily CBM imagery ratings were compared to participants' response to CBM training (whether they were deemed a 'responder', as judged by variation in daily well-being measures across the different phases of the study; see Figure 5.3), and whether they demonstrated reliable and clinically significant change across time (as judged by differences in GAD-Q-IV scores; see Figures 5.4 and 5.5). Mann-Whitney U¹⁰ analyses found no statistically significant differences between the imagery scores and symptomology variation across time (see Table 5.1).

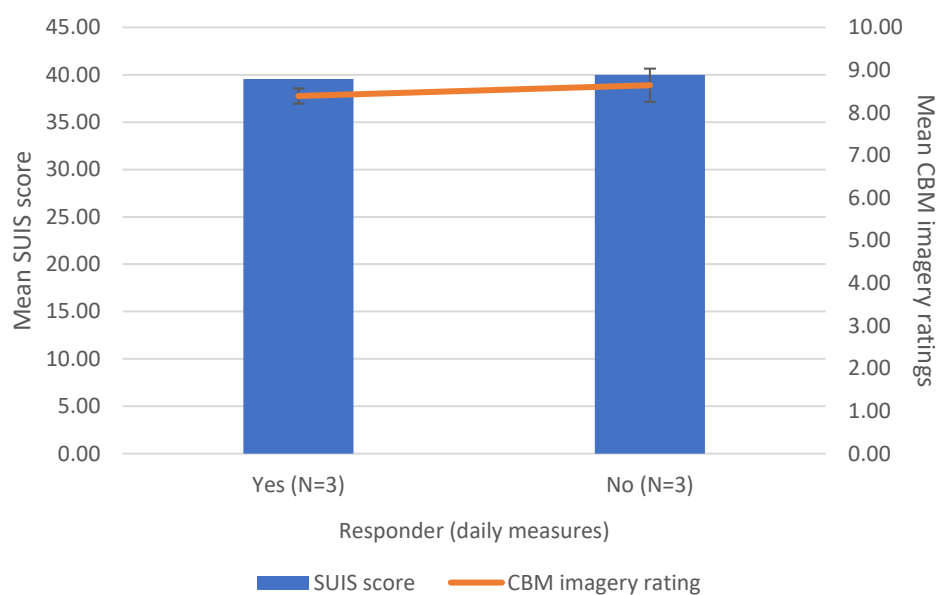


Figure 5.3. Comparison between imagery scores and 'responder' status according to variation in daily measures across the different study phases

¹⁰ Non-parametric analyses were conducted in recognition of the fact that the study data violated the statistical assumptions of parametric testing.

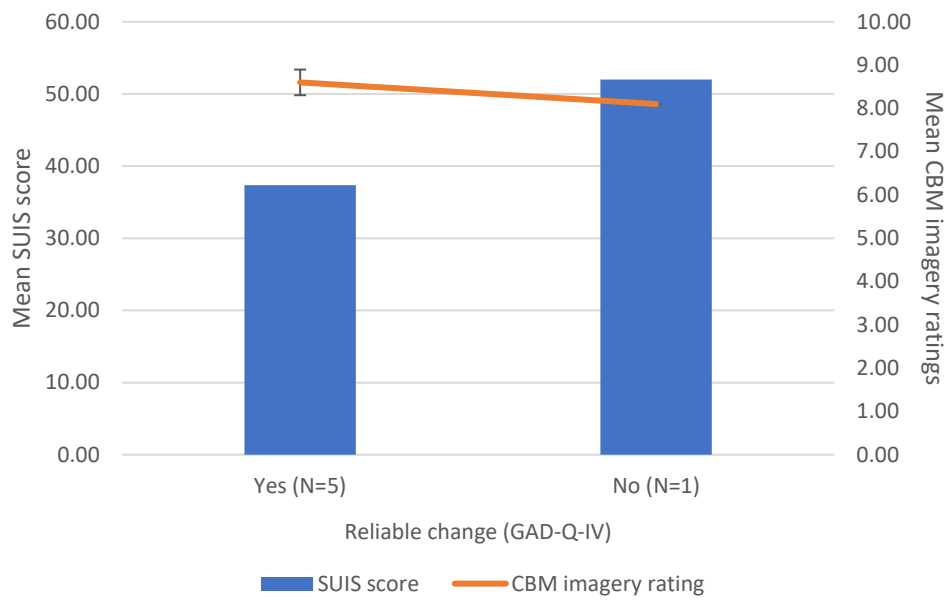


Figure 5.4. Comparison between imagery scores and incidence of reliable change in GAD-Q-IV scores

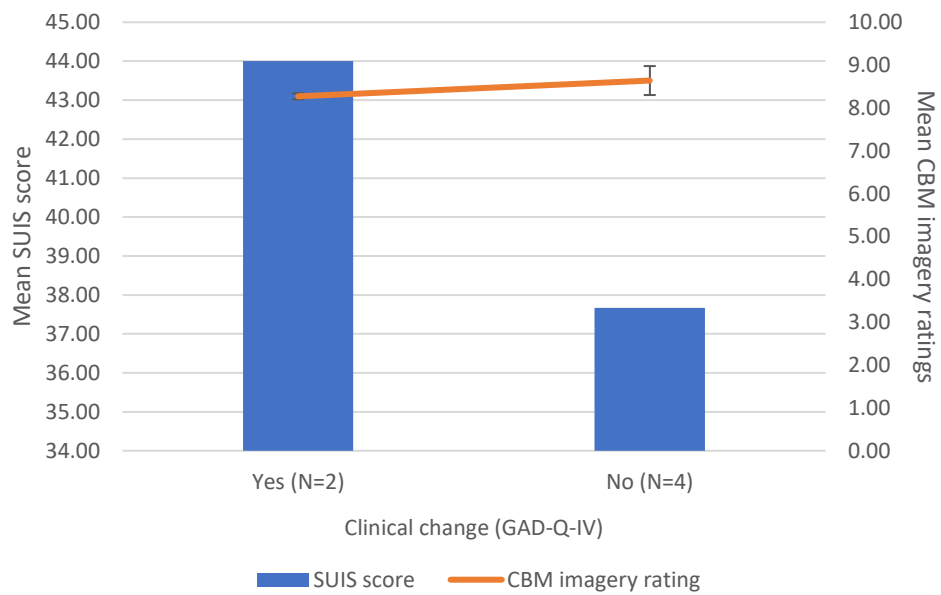


Figure 5.5. Comparison between imagery scores and incidence of clinically significant change in GAD-Q-IV scores

Table 5.1

Mann-Whitney U analyses testing differences between imagery scores and change in symptomology

	SUIS scores		Mean CBM imagery rating	
	<i>U</i>	<i>p</i>	<i>U</i>	<i>p</i>
'Responder' status	4	0.83	3	0.51
Reliable change incidence	0	0.14	0	0.14
Clinically significant change incidence	2	0.36	2	0.36

A Spearman's Rho correlation was conducted on the two measures of imagery, and identified a significant negative relationship ($r_s(6) = -.89, p = .02$), indicating that higher scores on one measure were more commonly associated with lower scores on the other (see Figure 5.6).

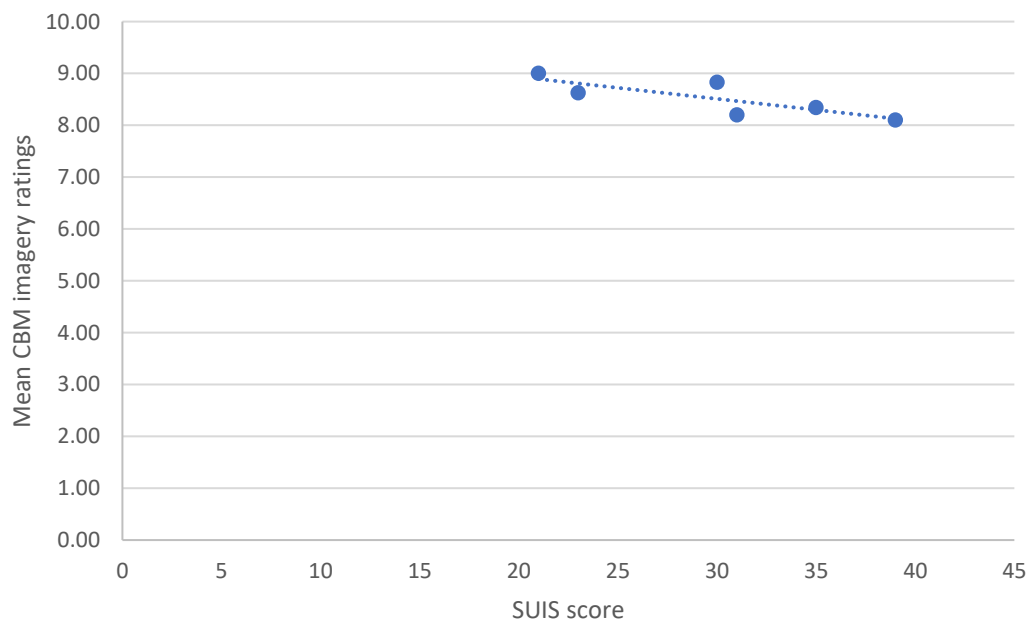


Figure 5.6. The relationship between different measures of imagery

Chapter 6. Overall Discussion and Critical Appraisal

This thesis set out to further understand the clinical potential of CBM methods by consolidating current evidence exploring the efficacy of home-based CBM training for interpretive biases. Furthermore, it aimed to extend understanding by examining this within an older adult sample. To the author's knowledge no existing studies have explored home-based CBM training with this population.

A systematic review investigated 12 published studies that had used home-based scenarios-based training paradigms, and found greater evidence of improvements when CBM targeted affective symptomology compared to anxiety-based difficulties. However, training-effects were seldom clearly apparent, and often only identified following more extensive or controlled analyses. This was commonly due to parallel improvements that were unexpectedly demonstrated in comparison control groups, both in terms of emotional pathology and changes in interpretive bias, which increased the challenge of isolating further training-specific differences.

An experimental study then sought to investigate the efficacy of a home-based interpretive CBM package for older adults with generalised anxiety symptomology; two areas that have received less focus in CBM research to date. Findings were mixed, supporting a stance that argues for some level of clinical utility but for caution in over-extending this claim. These findings shall now be considered in combination with additional results that were separately analysed and reported, followed by a collective discussion and critical evaluation of the field with recommendations for future research and focus.

6.1. Empirical Study

6.1.1. Engagement as a moderator of training utility. Findings from Chapter 5 alluded to a logical association between subjective anxiety related to using a computer to

access the CBM training and engagement in the task. Participants one and eight both reported higher levels of concern around using a computer and required an enhanced level of telephone support during the CBM training phase. Both participants additionally omitted a training session due to their difficulties operating the computer, with participant eight only partially completing a further two training sessions. Data taken from CBM training logs revealed a reduction in participant eight's ability to provide correct responses to word fragments and comprehension questions relating to each training scenario, although participant one's performance figures appeared more in line with other respondents. This suggests that, despite their mutual anxiety, only participant eight suffered poor engagement as a result. In support of this, both participants showed contrasting patterns of response in terms of changes in reported daily well-being during the training phase. Participant one was identified as a responder, with changes in GAD-Q-IV scores further indicating the presence of reliable but not clinically meaningful change. Alternatively, participant eight was classified as a non-responder, and was the only participant to show no improvement in either index of change. It seems reasonable, therefore, to speculate that engagement in training (and not receiving the full treatment) might at least partially moderate training efficacy. While this seems a rational supposition, it adds a layer of complexity to the debate surrounding the clinical utility of CBM; increasing the challenge of clarifying whether absence of effects represent genuine paradigm limitations or are an artefact caused by a disengaged or distracted audience.

6.1.2. Imagery. Contrary to prior research that posits imagery as a potential moderating factor of CBM efficacy (e.g. Holmes, Lang, & Shah, 2009), no evidence emerged from the present study to suggest any association between imagery and response to training. Of further interest, scores on the SUIS (a measure that captures typical use of mental imagery in daily life) were inversely correlated with mean participant ratings that represented

perceived ability to generate field perspective images of training scenarios. This finding might suggest that being issued with explicit instructions around *how* to use imagery might interact with an individual's natural proclivity to use it; serving as an aid to individuals with lower typical use of imagery whilst interfering with higher routine practice.

As identified in Chapter 1, it is worth noting that the emphasis on promoting the use of imagery in CBM originated from studies that explored CBM in individuals with depression (e.g. Holmes et al., 2009; Lang, Blackwell, Harmer, Davison, & Holmes, 2012). Indeed, Torkan et al. (2014) demonstrated the superior ability of imagery-focused CBM training to bring about improvements in depressive symptomology compared to identical positive CBM training that simply omitted an imagery element. Participants who received imagery-focused CBM also showed a significant reduction in rumination, which was absent in the non-imagery positive-CBM group. Of note, however, CBM training was delivered in an auditory manner through headphones for the above three studies. This followed research demonstrating that CBM adopting a more traditional delivery style that relied on verbally-based information processing (i.e. reading scenarios presented on a computer screen; Mathews & Mackintosh, 2000) produced no positive effects in depressive presentations (Holmes, Mathews, Dalgleish, & Mackintosh, 2006; Holmes et al., 2009).

The variation in presentation style used in imagery-focused CBM paradigms makes it difficult to determine the critical components responsible for the method's perceived success. In Mathews and Mackintosh's (2000) original CBM training, participants were actively engaged in the task through their completion of word fragments that resolved the inherent ambiguity of scenarios. From its inception, this active role has been identified and maintained as a key factor in the technique's success; without which, the authors were unable to replicate evidence of training effects (Mathews & Mackintosh, 2000; Hoppitt, Mathews, Yiend, & Mackintosh, 2010). As already discussed, the present study identified further evidence

supporting the critical role of engagement. Perhaps, therefore, the element of imagery focus in CBM training delivered through headphones maintains the active aspect to what would otherwise be a passive exercise.

Nevertheless, the coupling of an auditory delivery method of CBM that additionally combines an imagery focus has been reliably demonstrated to produce improvements in depressive symptomology (e.g. Lang et al., 2012; Torkan et al., 2014; Williams et al., 2015). In contrast, however, research has struggled to clearly replicate any greater potential for imagery- versus verbally-focused CBM training in anxiety-based presentations (e.g. Black & Grisham, 2016). Given the known verbal-linguistic manifestation to worry cognitions (Behar, Zuellig, & Borkovec, 2005), the traditional mode of presentation might realistically remain better suited to studies investigating CBM for GAD. Certainly, the results from the present study seem to correspond to these disorder-specific differences in the optimal delivery modality. Alternatively, there is evidence to suggest that the encouraged use of imagery might actually facilitate recovery from worry-based anxiety disorders. According to the cognitive avoidance theory of worry (Borkovec, Alcaine, & Behar, 2004), the use of a verbally-based processing style reduces the anxiety-activating presence of intrusive imagery. This is experienced as a positive outcome for the individual, which reinforces perceived worry utility. However, this practice over time reduces perceived ability to cope due to a lack of engagement with and emotional processing of feared outcomes (Foa & Kozak, 1986). Skodzik, Leopold, and Ehring (2017) have demonstrated the therapeutic effects of training worrisome individuals to adopt a more imagery-based processing style when experiencing worry. The challenge of combining this element into anxiety-targeted CBM packages, therefore, appears a justified direction for future focus.

6.2. Critical Evaluation

6.2.1. Design and conduct. Despite the challenges encountered in recruiting participants in to the study, and the relatively high attrition rate (40%) of consented participants, the resulting sample size of six satisfies the recommended minimal numbers necessary to test study hypotheses in single case series design (at least five individuals, Gerring, 2007; between six and ten individuals, Rowley, 2002). Further, the extensive a-priori randomisation procedures (baseline length; SST word-string selection and order; counterbalancing of CBM training scenario order) represent a notable strength of the current study conduct, and increase internal validity (Kratochwill & Levin, 2010). The study additionally featured recognised single case methodological qualities, such as having a clearly defined research question, study sample, and intervention, as well as the use of appropriate and reliable outcome measures (Carey & Boden, 2003).

However, the research was not without fault: one argued criticism of the follow-up phase as employed in the current study, is that it represented the only phase of the study involving no novel learning of procedures. The daily requirements mirrored those of the baseline phase; completion of daily measures and the SST. It is possible, certainly for a group of individuals with recognised propensities towards anxiety and future-focused worry, that the familiarity of this stage served as an artificial pacifier to reported distress. In support of this conjecture, with the exception of participants six and eight, variability in individuals' daily well-being measures appeared less pronounced during the follow-up phase. Moreover, for participants one and two, variability in these measures during the first two study phases show a pattern involving an initial rise and subsequent fall in reported severity. This might represent a habituation to their participation commitments within the respective study phases, which would obviously create artificial noise in the data. Without a control comparison group or captured information relating to additional life events experienced during these study

phases, such an inference must remain without further clarification, however future research might profit from trying to maintain a better consistency of novelty across study phases.

The present study would have been strengthened by having greater than two comparison points for the GAD-Q-IV. Ideally, assessment points would have been matched for both primary outcome variables, resulting in the SST and GAD-Q-IV being measured simultaneously. The GAD-Q-IV featured as a key eligibility measure and so was necessarily completed at the first in-person meeting. For this reason, perhaps an optimal solution in retrospect would be simply to add an alternative primary outcome measure to each measurement point of interpretive bias. This would provide concurrent data on GAD symptomology and interpretive bias, while also permitting exploration of the overall change on GAD-IV-Q scores (pre- and post-study, as was currently formatted). An example of a potentially suitable measure for this purpose would be the Penn State Worry Questionnaire (Meyer, Miller, Metzger, & Borkovec, 1990) or the abbreviated version of this item (Hopko et al., 2003), which is quicker to complete and has demonstrated good psychometric properties in older adult samples (Crittendon & Hopko, 2006; Wuthrich, Johnco, & Knight, 2014).

Further, the two standardised measures here implemented to monitor daily variation in subjective symptomology, the PHQ-9 and GAD-7, were originally designed to capture typical symptom severity across a retrospective period of two weeks. Alternatively, it was here applied to monitor experiences across a preceding 24-hour period. The psychometric properties of these measures have not been reliably established across this shorter timeframe. However, given that these measures were used to identify change across time within individuals, this issue arguably warrants less concern in terms of the potential for varying interpretations between individuals. Nevertheless, although the present design employed multiple measures of daily well-being, the absence of research exploring the application of

these measures in such a way means that it is not possible to rule out issues around reduced sensitivity or the presence of response biases over time that might confound data integrity here.

In-depth analyses of individual performance combined with qualitative feedback provided rich information that afforded an understanding of irregular and unforeseen patterns in the data. This proved especially useful, for example, in ascertaining likely reasons *why* CBM appeared unhelpful for some participants, such as their difficulties engaging with the training. While it is clearly not a failsafe method, as evidenced through the incongruent technical logging and subjective reporting regarding participant six's completion of CBM training, the ability to measure and analyse data to such fine detail is a key strength afforded through single case series design. This offers access to an indispensable array of information relating to factors that seem critical to the success of the technique's development.

6.3. Theoretical and Clinical Implications

6.3.1. CBM and GAD. With the finding that GAD has received considerably less research focus over the past 15 years compared to other anxiety disorders (Dugas, Anderson, Deschenes, & Donegan, 2010), it seems unsurprising that the key defining mechanisms underlying GAD remain somewhat in debate. For example, Fergus and Wu (2010) posit that a key cognitive process underlying GAD involves an intolerance of uncertainty, while others claim that this forms a transdiagnostic feature common to all anxiety disorders (Anderson et al., 2012; McEvoy & Mahoney, 2011).

Known central attributes of GAD include a tendency to worry disproportionately and to an uncontrollable level (e.g. Ruscio & Borkovec, 2004). As already mentioned, the cognitive avoidance theory of worry (Borkovec et al., 2004) posits that this serves a protective function to perceived future threat. Similar perceived protective functions of worry

are conceptualised through the meta-cognitive model of GAD (Wells, 1995) and the experiential avoidance model of worry (Newman & Llera, 2011), which both describe individuals' positive beliefs around worry utility (e.g. *worrying helps prepare me*). These theories reason that the process of cognitive avoidance paradoxically maintains the cycle of anxiety by preventing emotional exposure that might otherwise lead to emotional habituation and facilitate cognitive review of anticipated fears and capacity to cope (Behar, DiMarco, Hekler, Mohlman, & Staples, 2009).

With this in mind, CBM may prove less effective in helping to permanently modify maladaptive interpretive biases typically seen in GAD through the lack of focus around subjective meta-beliefs of worry. This would usefully be investigated through a longer follow-up phase to monitor the robustness of any change. Alternatively, CBM packages for GAD might benefit from incorporating aspects of these meta-beliefs directly into training content to encourage recognition of their prominence and impact. A similar challenge in developing CBM training specific to GAD-type concerns relates to the typical breadth of worry topics experienced compared to other anxiety disorders. A simple solution to this might involve increasing the breadth of (and, thus, exposure to) topics covered in CBM paradigms, which might mean that GAD packages involve longer or more intensive training schedules. Alternatively, perhaps a mixed method of CBM may prove useful in modifying worry-focused interpretive biases. For example, Hirsch, Hayes, and Mathews (2009) successfully reduced intrusive thought frequency and related anxiety in a sample of high-worriers using a training package that combined ambiguous scenarios training with ambiguous homograph training. During the homograph training component, participants were similarly tasked with completing word fragments that appeared on a screen, in this instance precipitated by a homograph priming word; one that contains both a threat-relevant and neutral meaning (e.g. *batter*). This combination of methods might facilitate targeting both of

instant threat-focused biases through homograph training modules, and threat-biases that are more gradually activated through scenarios-based components.

The proposed solutions described above can be criticised for having a reductionist view of the phenomenology of GAD, which fails to account for differences in how individuals might engage with CBM training due to the nature of their worries. For example, the global propensity to worry is likely to lead to behavioural and/or cognitive avoidance in fully engaging with the training content. This might partially explain the high attrition rates experienced in the current experimental study. Encouraging recognition of these patterns forms a critical focus and challenge to traditional forms of psychotherapy, which is ultimately not afforded through the simple design and independent practice of CBM. This supports the use of the paradigm as an adjunctive aid rather than as a standalone therapeutic treatment option.

Regardless of the specific mechanisms that precipitate or maintain pathological worry, GAD seems to be characterised by an impairment in the efficient and accurate processing of threat-related stimuli (MacNamara & Hajcak, 2010). CBM paradigms may therefore offer a graded method of exposing individuals to low level hypothetical threat (ambiguity) and providing them with an opportunity to practice accessing non-threat meanings. Graded exposure treatments have proven to be popular and effective in other anxiety-based disorders (e.g. Otte, 2011). Therefore, it might reasonably hold potential here as a strategy through which individuals can start to recognise the extent of their biased information processing. It is possible that this process of facilitating recognition of biased patterns in thinking alone (as feedback from participant six suggests) might have influenced the unanticipated improvements that control training has frequently shown to produce (e.g. Blackwell et al., 2015; Salemink, Kindt, Rienties, & van den Hout, 2014).

6.3.2. CBM in an older adult population. Lower prevalence rates for GAD have been recorded in older adults compared with a younger age cohort (Mackenzie, Reynolds, Chou, Pagura, & Sareen, 2011). However, diagnostic methods have been criticised as being indiscriminate to the emotional and functional impairment caused by subthreshold anxiety in later life (Lenze & Wetherell, 2011). When considered with the fact that such individuals commonly avoid seeking professional help for these difficulties (Mackenzie et al., 2011; Prévile et al., 2008), actual incidence is likely to be far greater than figures suggest. Research has demonstrated that age is not a predictor of treatment success: psychological therapies, such as CBT (Gonçalves & Byrne, 2012) and ACT (Wetherell et al., 2011), pharmacology alone, and combined options (Gonçalves & Byrne, 2012) are all evidenced as effective treatments for reducing clinical anxiety in older adults. Subjectively, older adults report being more drawn to options that exclude medication as an initial treatment option (Gaudreau, Landreville, Carmichael, Champagne, & Camateros, 2015; Mohlman, 2012).

While not directly comparing against other available treatment options, participants in the empirical study reported here provided positive ratings relating to factors around the acceptability of CBM training. Similarly, participant views indicated a low anticipation of deterrence by other adults in their age cohort as a result of the use of a computer to deliver CBM; even when they reported concern around this element themselves. This finding is particularly encouraging given that the current cohort of older adults is less likely to use computers in everyday life (e.g. Selwyn, Gorard, Furlong, & Madden, 2003) or to have used computers growing up or through their working adult life, compared with younger generations. Participants' general ability to independently manage home-based computer training combined with their subjective response to it suggest no reason why CBM should be dismissed as an option for cognitively able older adults. However, evidence did emerge to link computer-based anxiety to engagement and efficacy of CBM training. This might

suggest that older adults, or specifically individuals with less familiarity using technology, might benefit from increased training provision prior to engaging with CBM, as well as increased support during the active stage.

The point above seems especially pertinent given that the present sample was composed of individuals who themselves were not deterred from participating in a study that involved using computers. Alternatively, this featured as the primary reason given by individuals who seemed to meet inclusion criteria but opted not to participate. This fundamental selection bias clearly limits any speculation around the extent to which CBM may or may not be suitable to a more general sample of older adults. However, considering evidence that recognises the potential for alternative computerised forms of psychological interventions in this age cohort (e.g. Dear et al., 2015; Landreville, Gosselin, Greiner, Hudon, & Lorrain, 2016; Titov et al., 2015), it is possible that the gap at least partially resides between an individual's physical ability and cognitive capacity to engage with computer-delivered interventions and their perception of and confidence around this.

In retrospect, this study could be criticised for over-extending its aim by exploring too many lesser represented areas in the literature: the efficacy of CBM (1) in a naturalistic environment, (2) using an older adult population, and (3) with a primary focus around generalised anxiety symptomology. Perhaps a better approach might have involved a more balanced inclusion of originality, such as by trying to replicate and extend the findings of Murphy et al. (2015) by focusing on older adults with GAD symptomology but who complete their CBM training at a research facility. It would be interesting to explore whether the increased provision of support available through such a design might have enabled greater engagement with the training. While increased telephone support was offered to participants in the present study who struggled with using the computer, the medium of delivering this permitted less effective reassurance and guidance. Further exploration of this issue would

reveal useful information pertaining to the optimal level of support required for individuals to benefit from CBM training.

6.4. Future Direction of CBM

While firm conclusions relating to the overall limits in the clinical potential of CBM cannot be reached at this stage in the techniques development, the systematic review and empirical study described here can usefully inform future key directions that might position the field closer towards such application. Evidence presented here generally justifies continued effort towards developing a package of CBM that functions to enhance current practice. For example, one conceivable manner in which CBM might complement CBT is through their respective balance of implicit learning with the explicit and deliberate focus that the more traditional therapy adopts (Brosan, Hoppitt, Shelfer, Sillence & Mackintosh, 2011; Hayes, Hirsch, Krebs, & Mathews, 2010). Evidence of this synergistic potential has recently been found by Capron, Norr, Allan, and Schmidt (2017), who demonstrated a reduction in anxiety sensitivity following a combined psychoeducation and CBM intervention.

Despite these encouraging advances, there remains a lack of consistency and general consensus around the ideal format for delivering CBM training, with published studies to date varying widely in the length of individual training sessions, number of overall training sessions and spacing between these, specific training exercises used to modify biases, as well as the use of focused versus combined training packages. This is by no means an exhaustive list, and highlights a need for a more coherent approach so that findings might form a reliable and collective body of data through which advances can be made.

An additional area that remains to be explored relates to the investigation around cognitive functioning and CBM suitability. With the knowledge of lifespan-related changes in information processing abilities, having an improved understanding of potential

moderators for how individuals respond to CBM would be helpful. This investigation would be relevant in thinking about the potential application of CBM both in older adult populations, but also in populations with specific cognitive impairments, such as learning disabilities, brain injury, or dementia-related difficulties. Such research might focus on cognitive domains such as attention, memory, visuospatial abilities, executive functioning, or language fluency, which might yield a more comprehensive understanding of the underpinning mechanisms that CBM influences.

Although the technique was originally explored amongst anxious presentations (Mathews & Mackintosh, 2000), recent efforts to refine CBM training as an aid to depressive interpretive biases have resulted in several randomised controlled trials being published (e.g. Blackwell et al., 2015; Williams, Blackwell, Mackenzie, Holmes, & Andrews, 2013; Williams et al., 2015), which appear to adopt a more consistently applied format of CBM training. This is possibly due to the involvement of several research-active individuals and teams that have driven the field over the past few years, however their efforts have clearly advanced understanding in a meaningful way.

Since its inception, the potential of CBM has tended to be exclusively explored as an intervention to reduce emotional pathology by training a more positive interpretive bias. Recently, interest has arisen as to whether the technique might offer a means to improve practice of health-beneficial behaviours by *increasing* individuals' threat-focus around certain topics. For example, Notebaert, Chrystal, Clarke, Holmes, and MacLeod (2013) explored whether the adaptive role of worry could be manipulated to influence behaviours around protecting skin from sun damage. This study serves a useful reminder of the underlying purpose of emotions such as anxiety; to guard individuals from threat. In instances where the dangers of particular lifestyle choices are relatively well-known but continue to be routinely ignored in society (e.g. poor diets, inactivity, smoking, alcohol consumption,

dangerous driving behaviours), CBM might offer a useful way of rebalancing threat biases in a manner that reduces cognitive dissonance and improves health behaviours. This could present a profitable avenue for application of the technique, given the known strain that such behaviours place on the health service (Scarborough et al., 2011).

6.5. Overall Conclusions

The field of CBM research has now spanned nearly two decades, yet the methods continue to attract interest and financial investment through large scale trials aimed at exploring the clinical applicability of the technique. While some critics have argued that the approach holds little to no potential as a therapeutic tool, such a sustained focus and emerging evidence base provides a strong argument in opposition of this claim. While few CBM researchers would contend that the method offers a replacement to traditional practice, there is mounting evidence supporting its use as a potential supplementary aid to current psychological interventions. Findings presented here provide initial evidence of the method's utility in older adult populations. Where future research continues to explore the boundaries to CBM's potential, these efforts should therefore include appropriate age representation from across the lifespan.

In recognition of the current state of progress in the field, this thesis has primarily focused on studies that offer CBM as an independently managed package accessed in home environments. For the method to meet its proposed objectives as a low-resource option, research must continue to investigate the extent to which observed effects can be generalised from controlled laboratory conditions into distraction-laden naturalistic settings. A key finding revealed through the empirical study reported here alludes to the importance of maintaining engagement with the task. Barriers to engagement are likely to vary according to presentation and population demographics, highlighting the importance of exploring

participants' phenomenological experience of completing CBM as well as statistical effects.

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Appendix A

Journal of Anxiety Disorder Author Guidelines



JOURNAL OF ANXIETY DISORDERS

AUTHOR INFORMATION PACK

TABLE OF CONTENTS

• Description	p.1
• Audience	p.1
• Impact Factor	p.1
• Abstracting and Indexing	p.2
• Editorial Board	p.2
• Guide for Authors	p.4



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Journal of Anxiety Disorders is an interdisciplinary journal that publishes research papers dealing with all aspects of anxiety disorders for all age groups (child, adolescent, adult and geriatric). Manuscripts that focus on disorders formerly categorized as anxiety disorders (obsessive-compulsive disorder, posttraumatic stress disorder) and the new category of illness anxiety disorder are also within the scope of the journal. Research areas of focus include: traditional, behavioral, cognitive and biological assessment; diagnosis and classification; psychosocial and psychopharmacological treatment; genetics; epidemiology; and prevention. Theoretical and review articles that contribute substantially to current knowledge in the field are appropriate for submission.

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Additional Information

Editorial guidance

The *Journal of Anxiety Disorders* publishes articles of relevance to the epidemiology, psychopathology, etiology, assessment, treatment, and prevention of anxiety and related disorders in both child and adult populations. The format of the articles includes randomized controlled trials, single case clinical outcome studies, theoretical expositions, epidemiological studies, investigations of early mechanisms of risk, genetic and biomarker studies, neuroimaging studies, critical literature reviews, meta-analyses, and dissemination and implementation studies. We are also interested in evaluations

of novel treatment delivery strategies, including the use of information technologies. Authors are encouraged to use methodologically rigorous sampling, structured or semistructured diagnostic interviews, randomization, therapist fidelity, and inter-rater reliability procedures where appropriate. Given limited journal space, we can accept only a limited number of studies, and we prefer to publish studies of clinical or community samples. However, we recognize that studies using other samples (e.g., undergraduate analogues) can provide meaningful increments to knowledge. Therefore, while emphasizing our preference for clinical or community samples that are most appropriate for the question under study, we will consider studies using other samples in so far as we judge them to make a significant incremental contribution to the understanding of anxiety and related disorders or anxiety psychopathology more broadly.

REVISED SUBMISSIONS

Article structure

Subdivision - numbered sections

Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to 'the text'. Any subsection may be given a brief heading. Each heading should appear on its own separate line.

Introduction

State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

Material and methods

Provide sufficient detail to allow the work to be reproduced. Methods already published should be indicated by a reference: only relevant modifications should be described.

Theory/calculation

A Theory section should extend, not repeat, the background to the article already dealt with in the Introduction and lay the foundation for further work. In contrast, a Calculation section represents a practical development from a theoretical basis.

Results

Results should be clear and concise.

Discussion

This should explore the significance of the results of the work, not repeat them. A combined Results and Discussion section is often appropriate. Avoid extensive citations and discussion of published literature.

Conclusions

The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

Appendices

If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information

- The title page must be the first page of the manuscript file.

Title. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible. **Author names and affiliations.** Where the family name may be ambiguous (e.g., a double name), please indicate this clearly. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name, and, if available, the e-mail address of each author. **Corresponding author.** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. **Ensure that telephone and fax numbers (with country and area code) are provided in addition to the e-mail address and the complete postal address.** **Present/permanent address.** If an author has moved since the work described in the article was done, or was visiting at the time, a "Present address" (or "Permanent address") may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

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A concise and factual abstract is required. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself. The abstract should not exceed 200 words in length and should be submitted on a separate page following the title page.

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Include a list of four to six keywords following the Abstract. Keywords should be selected from the APA list of index descriptors unless otherwise approved by the Editor.

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Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

Acknowledgements

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

Formatting of funding sources

List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Appendix B

Health Research Authority Approval


Health Research Authority
Research Ethics Service
London - Hampstead Research Ethics Committee
Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ
Telephone: 0207 104 8002

18 December 2015

Dr Katherine Bristow
Trainee Clinical Psychologist
National Health Service
Norwich Medical School
University of East Anglia
Norwich Research Park, Norwich
NR4 7TJ

Dear Dr Bristow

Study title:	The influence of Cognitive Bias Modification (CBM-I) on generalised anxiety symptomatology in older adults
REC reference:	15/LO/2159
Protocol number:	N/A
IRAS project ID:	183255

Thank you for your letter of 18 December 2015, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Assistant Miss Amber Ecclestone, nrescommittee.london-hampstead@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start

A Research Ethics Committee established by the Health Research Authority

of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Study poster]	1	03 July 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance and Indemnity letter]		
GP/consultant information sheets or letters	1	03 July 2015
IRAS Checklist XML [Checklist_18122015]		18 December 2015
Other [Professionals information sheet]	1	03 July 2015
Other [Study academic review letter]		04 August 2015
Other [Study participation calendar]	1	03 July 2015
Other [Participation instructions]	1	03 July 2015
Other [Study academic review feedback]	1	07 July 2015
Other [CBMI Screenshots]	1	03 December 2015
Other [REC PO - Amendments guide]	1	18 December 2015
Other [Study questionnaires]	1	18 December 2015
Participant consent form	1	03 July 2015
Participant consent form [consent to contact form]	1	03 July 2015
Participant information sheet (PIS) [Participant information sheet]	2	18 December 2015
REC Application Form	5.2.0	27 November 2015
Research protocol or project proposal	1	07 July 2015
Summary CV for Chief Investigator (CI) [Katherine Bristow]		
Summary CV for supervisor (student research) [Margo Ononaiye]		
Summary CV for supervisor (student research) [Adrian Leddy]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol

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- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance>

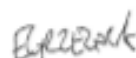
We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/LO/2159

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely



**On behalf of
Miss Stephanie Ellis
Chair**

Email: nrescommittee.london-hampstead@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Mrs Sue Steel

Dr Bonnie Teague,
Norfolk and Suffolk NHS Foundation Trust

Appendix C

CPFT Research and Development Approval

Cambridgeshire and Peterborough 
NHS Foundation Trust

Understanding mental health, understanding people

Research and Development Department

R&D Ref: M00723

Dr. Katherine Bristow
Trainee Clinical Psychologist
National Health Service
Norwich Medical School
University of East Anglia
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Joint Research Office
Box 277
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Direct Dial: 01223 596371 ext 6371
E-mail: mary-beth.sherwood@cpft.nhs.uk
www.cpft.nhs.uk

21 January 2016

Dear Dr. Bristow

Re: 15/LO/2159 The influence of Cognitive Bias Modification (CBM-I) on generalised anxiety symptomatology in older adults

In accordance with the Department of Health's Research Governance Framework for Health and Social Care, all research projects taking place within the Trust must receive a favourable opinion from an ethics committee and approval from the Department of Research and Development (R&D) prior to commencement.

R&D have reviewed the documentation submitted for this project, and has undertaken a **site specific assessment** based on the information provided in the SSI form, and I am pleased to inform you that we have no objection to the research proceeding within CPFT.

Sponsor: University of East Anglia

Funder: Standalone Project – no external funding

End date: 01/01/2017

Protocol: Version IRAS Version 5.2.0 (01.12.2015)

Conditions of Trust Approval:

- The project must follow the agreed protocol and be conducted in accordance with all Trust Policies and Procedures especially those relating to research and data management. Any mobile devices used must also comply with Trust policies and procedures for encryption.
- You and your research team must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act

HQ Elizabeth House, Fulbourn Hospital, Cambridge CB21 5EF
T 01223 726789 F 01480 398501 www.cpft.nhs.uk

In partnership with the University of Cambridge



1998 and are aware of your responsibilities in relation to the Human Tissue Act 2004, Good Clinical Practice, the NHS Research Governance Framework for Health and Social Care, Second Edition April 2005 and any further legislation released during the time of this study.

- Members of the research team must have appropriate substantive or honorary contracts with the Trust prior to the study commencing. Any additional researchers who join the study at a later stage must also hold a suitable contract.
- You and your research team must provide to R&D, as soon as available, the date of first patient first visit.

If the project is a clinical trial under the European Union Clinical Trials Directive the following must also be complied with:

- the EU Directive on Clinical Trials (Directive 2001/20/EC) and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Regulations 2004;
- the EU Directive on Principles and Guidelines for Good Clinical Practice (EU Commission Directive 2005/28/EC); and UK's implementation of the Directive: The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006;

Amendments

Please ensure that you submit a copy of any amendments made to this study to the R&D Department.

Annual Report

It is obligatory that an annual report is submitted by the Chief Investigator to the research ethics committee, and we ask that a copy is sent to the R&D Department. The yearly period commences from the date of receiving a favourable opinion from the ethics committee.

Please refer to our website www.cpft.nhs.uk for all information relating to R&D including honorary contract forms, policies and procedures and data protection.

Should you require any further information please do not hesitate to contact us.

Yours sincerely



Stephen Kelleher
Senior R&D Manager

Cc'd

Dr. Margo Ononaiye, Norwich Medical School, University of East Anglia, Norwich
Research Park, NR4 7TJ (m.ononaiye@uea.ac.uk)

Appendix D

NSFT Research and Development Approval

Norfolk and Suffolk **NHS**

NHS Foundation Trust

Research and Development
The Knowledge Centre
Hellesdon Hospital
Drayton High Road
Norwich
NR6 5BE

Telephone 01603 421255

E mail: RDofficemailbox@nsft.nhs.uk

Dr Katherine Bristow
Trainee Clinical Psychologist
Norwich Medical School
University of East Anglia
Norwich
NR4 7TJ

14th January 2016

Dear Katherine,

Re: RD #16 183255: The influence of Cognitive Bias Modification (CBM-I) on generalised anxiety symptomatology in older adults

Thank you for submitting the above project for local research governance approval. I am pleased to inform you that your project has been given full approval and you may begin your research at the following site:

- Norfolk & Suffolk NHS Foundation Trust

I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign both copies returning one copy to the Research and Development office, at the above address, and keeping the other in your study file. Failure to return the standard terms and conditions may affect the conditions of approval. Under the agreed Standard Terms and Conditions of Approval you must inform the R&D department of any proposed changes to this study and submit annual progress reports to the R&D department.

Any researcher(s) whose substantive employer is not the Norfolk & Suffolk NHS Foundation Trust must have a Letter of Access or Honorary Research contract and evidence of Good Clinical Practice (GCP) training before coming on site to conduct their research in this project. Please note that you cannot take part in this study until you have this documentation. If a Letter of Access / Honorary Research Contract has not been issued – please contact us immediately.

If you have any queries regarding this or any other project, please contact, Tom Rhodes, Senior Research Facilitator, at the above address.

The reference number for this study is: **RD #15 183255**, and this should be quoted on all correspondence.

Yours sincerely,



Bonnie Teague
Research Manager



Chair: Gary Page
Chief Executive: Michael Scott
Trust Headquarters: Hellesdon Hospital,
Drayton High Road, Norwich, NR6 5BE
Tel: 01603 421421 Fax: 01603 421440 www.nsft.nhs.uk



Your research governance approval is valid providing you comply with the conditions set out below:

1. You commence your research within one year of the date of this letter. If you do not begin your work within this time, you will be required to resubmit your application.
2. You notify the Research and Development Office should you deviate or make changes to the approved documents.
3. You alert the Research and Development Office by contacting the address above, if significant developments occur as the study progresses, whether in relations to the safety of individuals or to scientific direction.
4. You complete and return the standard annual self-report study monitoring form when requested to do so at the end of each financial year. Failure to do this will result in the suspension of research governance approval.
5. You comply fully with the Department of Health Research Governance Framework and Trust Research Policies, and in particular that you ensure that you are aware of and fully discharge your responsibilities in respect to Data Protection, Health and Safety, financial probity, ethics and scientific quality. You should refer in particular to Sections 3.5 and 3.6 of the Research Governance Framework.
6. You ensure that all information regarding patients or staff remains secure and strictly confidential at all times. You ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice, Data Protection Act and Human Rights Act. Unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.
7. **UKCRN Portfolio Studies only:** You will make local Trust research team members aware that it is expected that the "first participant, first visit" date should be within 70 days of the full submission for Trust Research Governance Approval, and this date must be reported to the Research and Development office using the email address above. Delay to recruitment due to study-wide developments must be reported to the Trust as soon as possible.
8. **UKCRN Portfolio Studies only:** You will report and upload Trust recruitment to the UKCRN portfolio accurately and in a timely manner, and will provide recruitment figures to the Trust upon request.

Version Control

Document	Version	Date
Poster	1	03/07/15
GP letter	1	03/07/15
Information Sheet – Professional	1	03/07/15
Study Participant Calendar	1	03/07/15
Study Participant Instructions	1	03/07/15
Study Questionnaires	1	18/12/15
Consent Form	1	03/07/15
Consent Form: Consent to Contact	1	03/07/15
Information Sheet – Participant	2	18/12/15
Protocol	1	07/07/15
Example CBM-I Scenario	1	03/12/15




Chair: Gary Page
 Chief Executive: Michael Scott
 Trust Headquarters: Helleston Hospital,
 Drayton High Road, Norwich, NR6 5BE
 Tel: 01603 421421 Fax: 01603 421440 www.nsf.nhs.uk



Appendix E

NSFT Letter of Access

Norfolk and Suffolk 

NHS Foundation Trust

Research and Development

The Knowledge Centre

Hellesdon Hospital

Drayton High Road

Norwich

NR6 5BE

Telephone 01603 421255

E mail: RDofficemailbox@nsft.nhs.uk

Dr Katherine Bristow
Trainee Clinical Psychologist
Norwich Medical School
University of East Anglia
Norwich
NR4 7TJ

28th January 2016

Dear Katherine,

Re: NSFT Letter of Access for research - Re: RD #16 183255: The influence of Cognitive Bias Modification (CBM-I) on generalised anxiety symptomatology in older adults

This letter should be presented to each participating organisation before you commence your research at that site. The participating organisation is: **Norfolk and Suffolk NHS Foundation Trust.**

In accepting this letter, each participating organisation confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on **28th January 2016** and ends on **30th September 2017** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from **Norfolk and Suffolk NHS Foundation Trust**. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving confirmation from the individual organisation of their agreement to conduct the research.

The information supplied about your role in research at the organisation has been reviewed and you do not require an honorary research contract with the organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out. Evidence of checks should be available on request to the organisation.

You are considered to be a legal visitor to the organisations premises. You are not entitled to any form of payment or access to other benefits provided by the organisation or this organisation to employees and this letter does not give rise to any other relationship between you and the organisation, in particular that of an employee.

While undertaking research through the organisation you will remain accountable to your substantive employer but you are required to follow the reasonable instructions of the organisation or those instructions given on their behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by the organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with the organisations policies and procedures, which are available to you upon request, and the Research Governance Framework.



Chair: Gary Page
Chief Executive: Michael Scott
Trust Headquarters: Hellesdon Hospital,
Drayton High Road, Norwich, NR6 5BE
Tel: 01603 421421 Fax: 01603 421440 www.nsft.nhs.uk



You are required to co-operate with the organisation in discharging its/their duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on the organisations premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and each organisation prior to commencing your research role at that organisation.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the organisations premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that the organisation(s) do not accept responsibility for damage to or loss of personal property.

This organisation may revoke this letter and any organisation(s) may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of the organisation(s) or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

No organisation will indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in each participating organisation] and [the R&D office] in this organisation.

Yours sincerely



Bonnie Teague
Research Manager

cc: Resourcing, NSFT HR



Chair: Gary Page
Chief Executive: Michael Scott
Trust Headquarters: Hellesdon Hospital,
Drayton High Road, Norwich, NR6 5BE
Tel: 01603 421421 Fax: 01603 421440 www.nsft.nhs.uk



Appendix F

Professionals Information Sheet

Prof info v1; 03/07/2015



Professionals Information Sheet

The influence of cognitive bias modification (CBM-I) on generalised anxiety in older adults

Purpose of the study

This study is aiming to extend the current understanding of a computer programme called Cognitive Bias Modification for Interpretation (CBM-I). CBM-I is designed to target a person's natural tendency to perceive threat in their surrounding environment, which can be problematic for people who experience a lot of anxiety and worry. Research has found that reducing the degree to which people interpret threat around them also leads to a reduction in the amount of anxiety and worry that people experience. To date, this research has focused on younger adults and adolescents. The present study aims to discover whether the training is effective in reducing threat biases (and worry) in an older adult population.

Recruitment criteria

We are looking to recruit people aged 60 years old or above, who are fluent in written and spoken English and report struggling with anxiety and worry on a daily basis. They also need to be registered with a GP.

People **will not** be eligible for the study if they are currently receiving or about to receive a psychological intervention, have diagnosed or suspected cognitive impairment, or have a current or past diagnosis of psychosis or bipolar disorder.

Referral process

If you know of people you work with, who fit the eligibility criteria listed above, please let them know about the study. In the first instance, it is advisable to contact Kate Bristow (details listed below) with anonymous details to double-check eligibility. Following this, please give the suitable person a *Participant information sheet* for the study. If they are interested, they are invited to either get in touch with Kate directly or let you know. If they let you know, please make Kate aware so she can arrange to contact them.

Contact for further information

<u>Kate Bristow (chief researcher)</u> Email: k.bristow@uea.ac.uk Tel: [insert research mobile no]	<u>Margo Ononaive (research supervisor)</u> Email: m.ononaive@uea.ac.uk <u>Adrian Leddy (research supervisor)</u> Email: a.leddy@uea.ac.uk
--	--

Thank-you.

Appendix G

Participant Information Sheet

PI sheet v2; 18/12/2015



Participant Information Sheet

The influence of cognitive bias modification (CBM-I) on generalised anxiety in older adults

Chief researcher: Dr Kate Bristow (trainee clinical psychologist, UEA)

Research supervisors: Dr Margo Ononaiye (clinical psychologist, UEA); Dr Adrian Leddy (clinical psychologist, UEA)

Thank-you for taking the time to read through this information sheet!

Please feel free to discuss and share this with friends or family to help you decide whether you would like to take part in the study.

This study is being carried out as part of the necessary training for a Doctorate in Clinical Psychology at the University of East Anglia. It has been approved by the London-Hampstead Research Ethics Committee, and the Research and Development departments within Norfolk and Suffolk's (NSFT) and Cambridge and Peterborough's (CPFT) NHS Foundation Trust. It has also been reviewed by the *Inspire* panel, which consists of service users, the public, and local mental health organisation representatives.

Purpose of the study:

The study is looking at a type of training called Cognitive Bias Modification for Interpretation (CBM-I), which is a simple computer programme that focuses on how people interpret situations. CBM-I has been specifically designed for people who have a tendency to worry a lot. Research has looked at the effects of CBM-I using anxious people in the community and people who are receiving support from NHS services for their anxiety. This study is furthering the understanding of CBM-I training by only including adults aged 60 years and over who struggle with worry.

Why have I been invited to take part?

You have been invited to take part as you are aged 60 years old or above, and worry a lot.

Do I have to take part?

No, you do not have to take part in this study, and your NHS care or any groups you belong to will not be affected by your decision to participate or not. You will also still be welcome to consider participating in future research, whether or not you decide to take part in this study. If you decide to participate but change your mind, you can withdraw from the study. Further details of this can be found in the '*What happens if I no longer want to participate?*' section of this information sheet.

Do I need to have experience using computers to participate?

Participation in this study does not require a lot of previous experience of working with computers. The CBM-I programme is delivered on a computer, but you do not need to have one to participate as we can lend you a laptop with the programme already installed. Alternatively, it

might be possible to install the programme onto your home computer temporarily if you would prefer.

Training will be given by Kate (chief researcher) on how to access and use the programme (and laptop), until you feel comfortable and confident doing so yourself.


What taking part would involve:

If you register an interest in the study, the next stage would involve Kate phoning you to discuss the study in a bit more detail and answer any questions that you may have about it. At that stage, if you want to take part, Kate would arrange a time to visit you to go through some questionnaires with you. These ask about your levels of worry, your mood, your general mental health, and a measure of cognitive ability (e.g. memory and attention). This is **NOT** an intelligence test! You would be welcome to invite a friend or family member to join you in this appointment if you would like.

In order to take part, it would be necessary for you to commit to doing so over a block period of either 21, 23, or 25 days, which will depend on which group you are randomly assigned to. The groups differ only in their length of participation, not in the content or length of the CBM-I training.

If you take part, you would be asked to complete some questionnaires on a daily basis taking around 20-30 minutes. On seven days during the study, you will also be asked to complete a daily computer task, which lasts around 40-50 minutes. This will be explained to you in more detail at a later point, but is a simple task that entails reading through and imagining yourself in a series of scenarios and answering some basic questions about them. On three other days, you'll be asked to complete a separate computer task, which will take approximately 25-35 minutes. This will be explained in more detail at a later point, but is a simple task that involves making up basic sentences using a given list of words.

All of the study can be conducted in your own home. You can opt to receive daily reminders by phone/text to complete the questionnaires and computer tasks if that would be helpful.

1  Phone call with Kate to talk about the study

2 Face-to-face meeting to go through some questionnaires.



3: Taking part
(at home)



Day 1...



Daily questionnaires



Computer tasks on some days

...Day 25

4

thank you!

What happens if I no longer want to participate?

Should you decide that you no longer wanted to take part in the study, you can withdraw at any point up until we have the results for the study. This is expected to occur around two weeks after you have finished the study. To withdraw, you would simply need to contact any member of the research team. You are not obliged to provide any reason behind your decision, however if you are able to do so this might be helpful to enable us to learn for the future. Any decision to withdraw would not affect the service you receive from your NHS care team or local group, or future opportunities to participate in research.

What are the possible benefits of taking part?

You may or may not benefit by participating but by doing so you will be helping us to understand whether or not this may be a good treatment for people who worry.

To say thank-you for your time and effort, you will receive a £15 Boots, Marks and Spencer, or Amazon (your choice) voucher once you have completed the study.

What are the possible disadvantages and risks to taking part?

Similar studies have not identified any risks related to completing CBM-I training. The study does require a time commitment to complete the daily questionnaires and computer tasks.

Some questionnaires ask about quite sensitive topics, such as anxiety and mood, which can sometimes be upsetting for people. It is recommended that questionnaires are completed during the day, as telephone support is available during the weekday hours of 9am-5pm (see contact number provided for Kate below). This is provided for questions about your participation or practical elements to the study, or if you feel that you require further emotional support as a result of taking part in it. If this happens, it would be important for us to address this by talking about it in a bit more detail to see whether it is appropriate for you to continue in the study. At this point we might also talk about possible referrals to local organisations or NHS services for further support if appropriate.

Who will have access to my information?

All questionnaires and training data will be kept confidential. You will be allocated a research number, which will be linked to your consent form to enable all your data to be destroyed if you withdraw. All questionnaires and training data will only contain your research number, and will be stored securely and accessed only by Kate and the research supervisors (Margo and Adrian). Consent forms will be securely stored separately to any questionnaires or training data, and will be accessed only by Kate, Margo, and Adrian.

As an exception to the above information, if any information arises to suggest that you or someone else is at risk of harm (by yourself or others) this would be passed to the appropriate services. For this reason, we would need to inform your GP and any NHS mental health service that you receive support from that you are participating in the study.

All research data will be securely stored for ten years following the end of the study, in line with the UEA Research Data Management Policy.

How can I register my interest in the study?

If you would like to take part in the study or hear more about it, please complete the attached form and return it to your referrer (care co-ordinator or group leader). This will not commit you to participating to the study, but gives permission for your contact details to be passed on to Kate (chief researcher), who will then contact you by phone. Alternatively, you can contact Kate directly by phone or email using the details below.

Contact for further information:

<u>Kate Bristow (chief researcher)</u> Email: k.bristow@uea.ac.uk Tel: [insert research mobile no]	<u>Margo Ononaive (research supervisor)</u> Email: m.ononaive@uea.ac.uk <u>Adrian Leddy (research supervisor)</u> Email: a.leddy@uea.ac.uk
<u>UEA contact details for complaints procedure:</u> Professor Ken Laidlaw (Programme Director) Address: Norwich Medical School, University of East Anglia, Norwich Research Park, Norwich, Norfolk, NR4 7TJ Email: k.laidlaw@uea.ac.uk	

Appendix H

Consent to Contact Form

Consent to contact v1; 03/07/2015

Consent to Contact Form



The influence of cognitive bias modification (CBM-I) on generalised anxiety in older adults

Chief researcher: Dr Kate Bristow (trainee clinical psychologist, UEA)

Research supervisors: Dr Margo Ononaiye (clinical psychologist, UEA); Dr Adrian Leddy (clinical psychologist, UEA)

I would like to register my interest in the above study. By completing the details below, I am consenting to the chief researcher (Kate Bristow) contacting me to provide further information. I understand that this does not commit me to the study in any way.

Name: _____

Gender: Male / Female / Other

Age:

Please contact me on:

Phone (home): _____

Phone (other): _____

Email: _____

Useful information (e.g. best times of availability):

Please return this completed form to your care co-ordinator/group leader, who will pass it on to Kate Bristow.

Thank-you

Appendix I

Study Consent Form

Consent form v1; 03/07/2015



Consent Form

The influence of cognitive bias modification (CBM-I) on generalised anxiety in older adults

Research ID: _____

Researcher: Dr Kate Bristow (trainee clinical psychologist, UEA)

Research supervisors: Dr Margo Ononaiye (clinical psychologist, UEA); Dr Adrian Leddy (clinical psychologist, UEA)

Please initial box

1. I confirm that I have read the information sheet dated [insert version no] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected. ☐
3. I agree to my General Practitioner and/or care co-ordinator (if you're supported by an NHS mental health service) being informed of my participation in the study. ☐
4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Researcher	Date	Signature

Appendix J

GAD-Q-IV Questionnaire

Generalised Anxiety Disorder Questionnaire

1. Do you experience excessive worry? Yes ____ No ____
2. Is your worry excessive in intensity, frequency, or amount of distress it causes?
Yes ____ No ____
3. Do you find it difficult to control your worry (or stop worrying) once it starts?
Yes ____ No ____
4. Do you worry excessively and uncontrollably about minor things such as being late for an appointment, minor repairs, homework, etc.?
Yes ____ No ____
5. Please list the most frequent topics about which you worry excessively and uncontrollably:
a. _____ d. _____
b. _____ e. _____
c. _____ f. _____
6. During the last six months, have you been bothered by excessive and uncontrollable worries more days than not?
Yes ____ No ____

IF YES, CONTINUE. IF NO, SKIP REMAINING QUESTIONS.

7. During the past six months, have you often been bothered by any of the following symptoms? Place a check next to each symptom that you have had more days than not:
____ Restlessness or feeling keyed up or on edge ____ Irritability
____ Difficulty falling/staying asleep or restless/unsatisfying sleep ____ Being easily fatigued
____ Difficulty concentrating or mind going blank ____ Muscle tension

8. How much do worry and physical symptoms interfere with your life, work, social activities, family, etc.? Circle one number:

0	1	2	3	4	5	6	7	8
<hr/>								
None		Mildly		Moderately		Severely		Very Severely

9. How much are you bothered by worry and physical symptoms (how much distress does it cause you)? Circle one number:

0	1	2	3	4	5	6	7	8
<hr/>								
No distress		Mild distress		Moderate distress		Severe distress		Very Severe distress

Appendix K

MoCA Screen

MONTREAL COGNITIVE ASSESSMENT (MOCA) Version 7.1 Original Version

NAME :
Education :
Sex :

Date of birth :
DATE :

VISUOSPATIAL / EXECUTIVE		POINTS	
		Copy cube <input type="checkbox"/>	Draw CLOCK (Ten past eleven) (3 points) <input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Contour	<input type="checkbox"/> Numbers
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Hands	___/5
NAMING		POINTS	
			___/3
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/3
MEMORY		POINTS	
Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.	FACE 1st trial 2nd trial	VELVET 1st trial 2nd trial	CHURCH 1st trial 2nd trial
	DAISY 1st trial 2nd trial	RED 1st trial 2nd trial	No points
ATTENTION		POINTS	
Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order	<input type="checkbox"/> 2 1 8 5 4	___/2	
Subject has to repeat them in the backward order	<input type="checkbox"/> 7 4 2	___/2	
Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors	<input type="checkbox"/> FBACMNAAJKLBAFAKDEAAAJAMOF AAB	___/1	
Serial 7 subtraction starting at 100	<input type="checkbox"/> 93 <input type="checkbox"/> 86 <input type="checkbox"/> 79 <input type="checkbox"/> 72 <input type="checkbox"/> 65	___/3	
4 or 5 correct subtractions: 3 pts , 2 or 3 correct: 2 pts , 1 correct: 1 pt , 0 correct: 0 pt			
LANGUAGE		POINTS	
Repeat : I only know that John is the one to help today.	<input type="checkbox"/>	___/2	
The cat always hid under the couch when dogs were in the room.	<input type="checkbox"/>	___/2	
Fluency / Name maximum number of words in one minute that begin with the letter F	<input type="checkbox"/> _____ (N ≥ 11 words)	___/1	
ABSTRACTION		POINTS	
Similarity between e.g. banana - orange = fruit	<input type="checkbox"/> train - bicycle <input type="checkbox"/> watch - ruler	___/2	
DELAYED RECALL		POINTS	
Has to recall words WITH NO CUE	FACE <input type="checkbox"/>	VELVET <input type="checkbox"/>	CHURCH <input type="checkbox"/>
	DAISY <input type="checkbox"/>	RED <input type="checkbox"/>	Points for UNCUE recall only
Optional	Category cue	<input type="checkbox"/>	<input type="checkbox"/>
	Multiple choice cue	<input type="checkbox"/>	<input type="checkbox"/>
ORIENTATION		POINTS	
<input type="checkbox"/> Date <input type="checkbox"/> Month <input type="checkbox"/> Year <input type="checkbox"/> Day <input type="checkbox"/> Place <input type="checkbox"/> City	___/6		
© Z.Nasreddine MD www.mocatest.org Normal ≥ 26 / 30		TOTAL ___/30	
Administered by: _____		Add 1 point if ≤ 12 yr edu	

Appendix L

Eligibility Log

Eligibility Log

Completed by chief researcher:

- 1) Participant number: _____
- 2) Fluent in written/spoken English? Yes ____ No ____
- 3) Registered with GP? Yes ____ No ____

Details: _____

- 4) Current/past diagnoses:
 - a. Psychotic disorder Yes ____ No ____
 - b. Bipolar disorder Yes ____ No ____
 - c. Neurodegenerative diseases (e.g. dementia) Yes ____ No ____
 - d. Alcohol dependency Yes ____ No ____
 - e. Drug dependency Yes ____ No ____

Further details of any of above: _____

- 5) History of:
 - a. Stroke Yes ____ No ____
 - b. Brain injury Yes ____ No ____

Further details of any of above: _____

- 6) Current use of:
 - a. Alcohol Yes ____ No ____

If yes, further details regarding consumption (volume, frequency, associated problems):

b. Illicit drugs Yes ____ No ____

If yes, further details regarding consumption (volume, frequency, associated problems):

7) Medication currently taking:

a. Take as prescribed? Yes ____ No ____

Appendix M

SUIS Questionnaire

Spontaneous Use of Imagery Scale

Please read each of the following descriptions and indicate the degree to which each is appropriate for you. Do not spend a lot of time thinking about each one, but respond based on your thoughts about how you do or do not perform each activity. If a description is always completely appropriate, please write "5"; if it is never appropriate, write "1"; if it is appropriate about half of the time, write "3"; and use the other numbers accordingly.

- _____ When going to a new place, I prefer directions that include detailed descriptions of landmarks (such as the size, shape, and colour of a petrol station) in addition to their names
- _____ If I catch a glance of a car that is partially hidden behind bushes, I automatically "complete" it, seeing the entire car in my mind's eye.
- _____ If I am looking for new furniture in a store, I always visualise what the furniture would look like in particular places in my home.
- _____ I prefer to read novels that lead me easily to visualise where the characters are and what they are doing instead of novels that are difficult to visualise.
- _____ When I think about visiting a relative, I almost always have a clear mental picture of him or her.
- _____ When relatively easy technical material is described in a text, I find illustrations distracting because they interfere with my ability to visualise the material.
- _____ If someone were to tell me two-digit numbers to add (e.g. 24 and 31), I would visualise them in order to add them.
- _____ Before I get dressed to go out, I first visualise what I will look like if I wear different combinations of clothes.
- _____ When I think about a series of errands I must do, I visualise the stores I will visit.
- _____ When I first hear a friend's voice, a visual image of him or her almost always springs to mind.
- _____ When I hear a radio announcer or DJ I've never actually seen, I usually find myself picturing what they might look like.
- _____ If I saw a car accident, I would visualize what had happened when later trying to recall the details.

GAD-7 Questionnaire

GAD-7

Over the <u>last 2 weeks</u> , how often have you been bothered by the following problems? (Use "✓" to indicate your answer)	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

(For office coding: Total Score $T_{\text{_____}} = \text{_____} + \text{_____} + \text{_____}$)

1

Appendix O

PHQ-9 Questionnaire

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(Use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____
=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all <input type="checkbox"/>	Somewhat difficult <input type="checkbox"/>	Very difficult <input type="checkbox"/>	Extremely difficult <input type="checkbox"/>
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Appendix P

VAS

Visual Analogue Scales

Daily Questionnaires Pack

Please mark anywhere along the line to indicate your answer for the following questions:

- 1.) How anxious have you felt over the past 24 hours?

Not at all _____ *Extremely*

- 2.) Over the past 24 hours, how much have you tended to expect the worse?

Never _____ *All the time*

CBM-I Training

Please mark anywhere along the line to indicate your answer for the following questions:

Please rate the extent to which you have felt able to imagine yourselves in the scenarios:

Not at all able _____ *Extremely able*

Please mark anywhere along the line to indicate your answer for the following questions:

Please rate your enjoyment of this task:

Not at all enjoyable _____ *Extremely enjoyable*

Appendix Q

CBM Evaluation Questionnaire

CBM-I Evaluation Questionnaire

Please place a mark on the lines below to reflect your answer to the questions. Please pay attention to the descriptions underneath each rating.

1. How easy did you find using the CBM-I computer task?

0 _____ 10
(Not at all) (Very easy)

2. Were the CBM-I instructions easy to follow and understand?

0 _____ 10
(Not at all clear) (Very clear)

3. How enjoyable were the CBM-I sessions?

0 _____ 10
(Very enjoyable) (Not at all enjoyable)

4. Did you feel that the sessions were manageable to do alongside your other everyday activities?

0 _____ 10
(Very manageable) (Unmanageable)

5. Did you notice yourself thinking any different about situations after the sessions?

0 _____ 10
(Not at all) (Very different)

6. Did you notice yourself behaving any different in situations after the sessions?

0 _____ 10
(Not at all) (Very different)

7. Did you notice yourself feeling any different in situations after the sessions?

0 _____ 10
(Not at all) (Very different)

Please turn over...

8. How concerned were you about using a computer to complete the CBM-I training when you first learned of this requirement?

0 _____ 10
(Very concerned) (Not at all)

9. How concerned did you feel about using a computer to complete the CBM-I training following the training on how to use the programme?

0 _____ 10
(Not at all) (Very concerned)

10. To what extent do you think the use of a computer to complete the CBM-I training would deter other adults aged 65 year old or over?

0 _____ 10
(Not at all) (Very much)

11. Please give any other comments about the CBM sessions?

Thank-you

Appendix R

Study Calendar Example

Study calendar v1; 03/07/2015

Study Calendar

The influence of cognitive bias modification (CBM-I) on generalised anxiety in older adults

M 06/02/17	T 07/02/17 DAY 1	W 08/02/17 DAY 2	Th 09/02/17 DAY 3	F 10/02/17 DAY 4	Sa 11/02/17 DAY 5	Su 12/02/17 DAY 6
M 13/02/17 DAY 7	T 14/02/17 DAY 8	W 15/02/17 DAY 9	Th 16/02/17 DAY 10	F 17/02/17 DAY 11	Sa 18/02/17 DAY 12	Su 19/02/17 DAY 13
M 20/02/17 DAY 14	T 21/02/17 DAY 15	W 22/02/17 DAY 16	Th 23/02/17 DAY 17	F 24/02/17 DAY 18	Sa 25/02/17 DAY 19	Su 26/02/17 DAY 20
M 27/02/17 DAY 21	T 28/02/17	W 01/03/17	Th 01/03/17	F 01/03/17	Sa 01/03/17	Su 01/03/17

